United States Court of Appeals

for the

District of Columbia Circuit

TRANSCRIPT OF RECORD

967

IN THE

UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 23,812

THE ENVIRONMENTAL DEFENSE FUND, INC., IRENE LOPEZ, ELVIRA GARDUNO, KATHY RADKE, MARILYN VITTOR, LEIGH ROYCROFT, and JUAN ZAMORA,
Petitioners,

v.

ROBERT H. FINCH,
Secretary, Health, Education and Welfare,
Respondent.

ON PETITION FOR REVIEW OF AN ORDER OF THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

BRIEF FOR PETITIONERS

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TABLE OF CONTENTS

*Cases or authorities chiefly relied upon.

AUTHORITIES CITED

Cases:

Page

Page

Page

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QUESTIONS PRESENTED

It is uncontroverted that the pesticide-chemical DDT causes cancer in test animals and is responsible for widespread environmental degradation including damage to nontarget organisms of many species, the preservation of which is essential to the well being of man. In response to evidence to this effect the Secretary of Health, Education, and Welfare not only refused to take immediate action to prohibit the further contamination of raw agricultural commodities with

DDT, he refused to even publish notice of petitioners' proposal in the *Federal Register*, thereby denying them access to the administrative procedures available under the Food, Drug and Cosmetic Act.

The questions presented are:

(1) Whether the Secretary must act immediately to prohibit the continued contamination of raw agricultural commodities by a pesticide-chemical which is established to be cancer-producing; and

(2) Whether, in view of the showing that DDT is a carcinogen and a hazard to human health generally, the Secretary properly could find that petitioners' had not presented "reasonable grounds" in support of their request that existing tolerances for DDT be repealed.

STATEMENT PURSUANT TO RULE 8(d)

Preliminary matters have already been considered and disposed of by the Court in this proceeding. Simultaneous with the filing of its Petition for Review, petitioners filed a "Motion to Advance on the Docket and to Expedite" consideration of this proceeding. On January 14, 1970, Judge McGowan directed that a request for an extension of time filed by respondent be treated as respondent's opposition to petitioners' Motion. On January 29, 1970, a panel of the Court consisting of Chief Judge Bazelon and Judge Robinson granted petitioners' motion, specified an expedited briefing schedule and directed the Clerk to set this proceeding down for early argument.

The same panel of the Court, also on January 29, 1970, directed the parties in No. 23813 *(Environmental Defense Fund, Inc., et al., v. Clifford M. Hardin)* to comply with the same expedited briefing schedule and instructed the Clerk to schedule the matter for early argument. Petitioners there challenge the failure of the Secretary of Agriculture to take actions under the Federal Insecticide, Fungicide and Roden-

ticide Act (61 Stat. 163, as amended, 7 U.S.C. 135, *et seq.*), to suspend and cancel the registrations of economic poisons containing DDT.

REFERENCES TO RULINGS

In this proceeding petitioners seek review of a determination by the Secretary of Health, Education, and Welfare under the Food, Drug and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. 301, *et seq*. This case comes to the Court as a result of the Secretary's refusal, announced on December 8, 1969, immediately to prohibit residues of the chemical-poison DDT on raw agricultural commodities. The Secretary's decision which is challenged in this Court is set forth at pp. 8-9 of this brief in the Joint Appendix at page A-98.

STATEMENT

A. Nature of this Proceeding

DDT is one of the most popular and widely studied of the of the pesticides.[1] It has been recognized for some time that DDT represents an extreme ecological hazard and, more recently, that it is cancer-producing in test animals. Petitioners, relying on evidence of these hazards, requested the Secretary to act now to protect the public health and well-being by eliminating the unnecessary ingestion of that poison.

The Commissioner of Food and Drugs, acting for the Secretary and without disputing the scientific evidence that DDT is a carcinogen and an environmental hazard generally, denied the petition refusing even to publish notice of petitioners' proposal in the *Federal Register* thereby depriving them of access to the administrative process.

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[1] "DDT", is a mixture of substances which has as its major ingredient the chemical compound 1,1,1-trichloro-2,2-bis-(p-chlorophenyl) ethane. DDT is widely used as a pesticide in a variety of economic poisons.

B. The Statutory and Regulatory Scheme

Petitioners filed their request for administrative action pursuant to Section 408 of the Food, Drug and Cosmetic Act, 21 U.S.C. 346a (hereinafter referred to as "Act"),[2] the pesticide provision. Essentially that provision precludes the use on raw agricultural commodities of pesticide-chemicals which are not generally recognized by "experts qualified by scientific training and experience" as being safe unless they are used within tolerance limits prescribed by the Secretary or pursuant to an exemption order. In establishing tolerances the Secretary is to give appropriate consideration to, among other factors, "the necessity for the production of an adequate, wholesome, and economical food supply [and] to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious." (Section 408(b), 21 U.S.C. 346a(b)). Where "the scientific data before [him] does not justify the establishment of a greater tolerance" the secretary may establish the tolerance at zero. (*ibid.*)

Tolerances have, over the years, been established for DDT residues on scores of raw agricultural commodities ranging from a tolerance level of zero to a high of 7 parts per million. See 21 CFR 120.147-120.147c.[3] However, under the regulations an interested person may request the repeal of existing tolerances and if "reasonable grounds" are presented in support of such a request the petitioner is entitled to have his proposal noticed in the *Federal Register* and otherwise to enjoy the protection of the administrative procedures. 21 CFR 120.32.

The instant case also involves application of the so-called Delaney anticancer amendment which requires the Secretary

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[2]Section 408, as well as the other relevant portions of the Act, are set forth in the Supplement to this brief.

[3]The relevant portions of the regulations are similarly included in the Supplement to this brief.

to prohibit the use of any chemical or additive which is shown to be capable of inducing cancer in test animals. The amendment is contained explicitly in the food additives section of the Act (Section 409(c)(3)(A), 21 U.S.C. 348(c)(3)(A)) and in the color additives section. (Section 706(b)(5)(B), 21 U.S.C. 376(b)(5)(B)).

C. The Petitioners

Petitioner, The Environmental Defense Fund, Incorporated (hereinafter "EDF"), is a nonprofit, tax-exempt membership corporation organized under the laws of the State of New York. EDF is made up of scientists and other citizens dedicated to the protection of man's environment, employing legal action where necessary. EDF has, through litigation, sought to protect the environment from various forms of pollution. Its Scientists Advisory Committee, with more than 200 members, including some of the world's foremost environmental scientists, assures that positions taken are thoroughly supported by scientific evidence. In its activities, EDF does not concern itself with the pecuniary interests of individuals; rather, it seeks to assure the preservation or restoration of environmental quality on behalf of the general public.

Petitioners Irene Lopez, Elvira Garduno, Kathy Radke, Marilyn Vittor and Leigh Roycroft are young mothers who have in the past, do presently, or intend in the future to nurse their children. It is an established fact, recently confirmed by the Commission on Pesticides and Their Relationship to Environmental Health,[4] that mothers' milk contains excessive amounts of DDT residues to the point where breastfed babies as a general rule are subjected to twice the maximum average daily intake of DDT recommended by the United Nation's World Health Organization (App. B-26, 27).[5]

[4] The so-called Mrak Commission.

[5] "App." references are to the separately bound Joint Appendix.

Petitioner Juan Zamora, the father of eight minor children, is an agricultural worker and as such is required to come into frequent contact with pesticide poisons. Again, the Mrak Commission corroborates that the dangers of DDT are considerably greater for those who must come into repeated contact with it as a consequence of their occupations (App. B-62, 63).

All of the individual petitioners reside in California, each is a consumer of food products, including raw agricultural commodities which contain residues of DDT, and each is economically disadvantaged.[5-A]

D. Prior Proceedings

1. *The Petition*

On October 7, 1969, a petition was filed requesting the issuance of a regulation repealing the tolerances for DDT on raw agricultural commodities. The petition was premised on the fact that DDT has been demonstrated to be cancer-producing in test animals with circumstantial evidence suggestive of possible carcinogenic effects in humans as well. Petitioners submitted, in support of their contentions, a comprehensive study recently completed under the sponsorship of the National Cancer Institute (the so-called *Innes* report)[6] which lays to rest any doubt as to the carcinogenicity of DDT in test animals. Additionally, petitioners submitted an earlier study which shows the carcinogenic potentialities of DDT when ingested by test animals over prolonged periods at dosage levels which approximate those to which the urban population is exposed,[7] and a study which

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[5-A] The Mrak Commission found that the hazards of DDT are compounded in the face of nutritional inadequacies.

[6] *Bioassay of Pesticides and Industrial Chemicals for Tumorigenicity in Mice: A Preliminary Note*, J. R. M. Innes, *et al.*, 41 Journal of the National Cancer Institute 1101 (June, 1969) (App. A-14).

[7] *Investigations on the Effects of Chronically Administered Small Amounts of DDT in Mice*, Kemeny and Tarian, 22 Experientia 748 (1966) (App. A-28).

suggests that DDT may well have carcinogenic effects in man.[8]

On October 31, 1969, petitioners submitted a supplemental filing requesting expedited action by the Secretary directed at prohibiting the continued presence of DDT in raw agricultural commodities. In recognition of the fact that the environment is already contaminated with DDT, thereby posing practical problems with respect to the realization of a zero tolerance, petitioners suggested action which the Secretary reasonably could take at this time so as to rid our food supply of DDT at the earliest date possible—the establishment of zero tolerance levels but exempting from seizure any commodities that contain residues arising from the application of DDT prior to the repeal of existing tolerances.

2. *The Mrak Commission Report*

In December, 1969, the Secretary received the final report of the Mrak Commission. In that report the Commission stated that "the evidence for the carcinogenicity of DDT in experimental animals is impressive and the [Technical Panel on Carcinogenesis] takes no exception to the conclusions as to DDT recorded in the JNCI report of the National Cancer Institute study" (the *Innes* study) (App. B-41).

The Commission reported that DDT residues are established nerve toxins and that they have acute effects on the central nervous system (App. B-21, 22, 25). More specifically, that DDT residues are responsible for the induction of metabolizing enzymes in the liver thus "alter[ing] the susceptibility to drugs or other chemicals that are normally metabolized by these enzymes" (App. B-61) and may, merely as a consequence of their accumulation in fatty tissue, "constitute a health hazard" (App. B-27).

[8] *Pesticide Concentrations in the Liver, Brain and Adipose Tissue of Terminal Hospital Patients*, J. L. Radomski, W. B. Deichmann, E. E. Clizer, 6 Food Cosmetics and Toxicology 209 (1968) (App. A-30).

Finally, after detailing the adverse effects of DDT residues on phytoplankton, beneficial insects, marine invertebrates, fish, birds and mammals (App. B-15), in some cases destroying entire species (App. B-8, 9, 15-17) the Commission warned (App. B-8):

> Man is an integral part of the living system, which includes about 200,000 species in the United States. Most of these are considered to be essential to the well-being of man. Pesticides are now affecting individuals, populations, and communities of natural organisms. Some, especially the persistent insecticidal chemicals such as DDT, have reduced the reproduction and survival of nontarget species.

3. *The Secretary's Decision*

By letter dated December 8, 1969, Herbert L. Ley, Jr., M.D., Commissioner of Food and Drugs, acting for the Secretary, advised petitioners that their request had been denied (App. A-98):

> This refers to Pesticide Petition No. OEO894, requesting that zero tolerances be established for residues of DDT on raw agricultural commodities.
>
> In a report to the Secretary of Health, Education, and Welfare, dated November 1969, the Commission on Pesticides and Their Relationship to Environmental Health recommends the elimination of all non-essential uses of DDT, i.e., its use be limited to the prevention or control of human disease and other essential uses for which there are no alternatives available. However, the Commission recognized that unavoidable residues of DDT from past uses will continue to be present in the soil, water, air and food supplies for a period of years, and thus that it is not practical to attempt to eliminate the residues of persistent pesticides from food by the establishment of zero tolerance limits. Plans are currently being developed to implement this recommendation of the Commission. We enclose a copy of the White House

> announcement of the Environmental Quality Council's review of the report by the Commission on Pesticides. We believe the steps outlined are the most reasonable steps that should be taken at this time.
>
> In the absence of a showing that establishing the zero tolerances you request would be practical, we find that you have not presented reasonable grounds to support the proposed action. Accordingly, a proposal based on the above petition is not being published.

The announcement of the Environmental Quality Council, relied upon by Dr. Ley, does not state that any affirmative action will be taken by the Secretary in response to the DDT menace.

STATUTES AND REGULATIONS INVOLVED

The pertinent parts of the Food, Drug and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. 301, *et seq*, and of the administrative regulations promulgated in implementation of that Act, 21 CFR Part 120, are set out in the Supplement to this brief.

ARGUMENT

INTRODUCTION AND SUMMARY

In testing the propriety of any action by the Secretary of Health, Education, and Welfare under the Food, Drug and Cosmetic Act, it is appropriate to focus first on the overriding objective sought to be accomplished by the Congress when it passed that legislation: protection of the health and welfare of the consuming public.

As stated by former Secretary Arthur S. Flemming, "there is one thing that a responsible government cannot do. It cannot fail to place at the top of its list of priorities the health of all of the people even though by so doing it may be or may appear to be acting against the economic interests of

a segment of our society. The government's paramount obligation to act in the interest of the health and safety of the people in administration of the food and drug laws was ably set forth by Justice Frankfurter"[9] when he said:

> The Food and Drug Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. *The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation* if it is to be treated as a working instrument and not merely as a collection of English words. [*United States v. Dotterweich*, 320 U.S. 277, 280, emphasis added.][10].

Confronted with a critical health problem which is completely "beyond self-protection" by the individual, the Sec-

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[9]Hearings on H.R. 7624 and S. 2197 before the House Committee on Interstate and Foreign Commerce, 86th Cong., 2d Sess. p. 42, hereinafter referred to as "*Hearings*."

[10]See, also: *62 Cases of Jam* v. *United States*, 340 U.S. 593, 596; *United States* v. *Sullivan*, 332 U.S. 689, 696; *United States* v. *Two Bags, Each Containing 110 Pounds, Poppy Seeds, et al.*, 147 F.2d 123, 127 (C.A. 6, 1945); *C. C. Co.* v. *United States*, 147 F.2d 820 (C.A. 5, 1945); and *United States* v. *30 Cases, Etc.*, 93 F. Supp. 764, 768-769 (S.D. Iowa, 1950).

In *C. C. Co.* v. *United States, supra*, the Fifth Circuit, in upholding condemnation of partially decomposed oysters, recognized (147 F.2d at 824):

> That statutes enacted for the public good and to suppress a public wrong, although they impose penalties or forfeitures, are not to be construed strictly in favor of the defendant but should be fairly and reasonably construed so as to carry out the intention of Congress. The Federal Food, Drug and Cosmetic Act was enacted in the interests of the public welfare to protect the public health, and the courts must give it effect according to its terms.

retary not only took a most restrictive reading of his responsibilities under the Act, he also completely foreclosed utilization of the administrative process.

As we show, where it is established that a pesticide-chemical is cancer-producing, the Secretary has no discretion but to immediately take all steps necessary to protect the public from the continued ingestion of that poison. It is uncontroverted that DDT is a carcinogen. Moreover, it is uncontroverted that DDT, wholly apart from its cancer causing effects, represents an acute hazard to the human liver and central nervous system and is seriously threatening a complete disruption of the entire biosphere through its adverse effects of the survival of many of the species which are considered to be essential to the well-being of man.

In the face of this showing, it was incumbent upon the Secretary to move now to rid our food supply of residues of DDT.

I

SUBSTANTIAL EVIDENCE ESTABLISHES THAT DDT IS A CANCER-PRODUCING SUBSTANCE; ACCORDINGLY, THE SECRETARY MUST ACT IMMEDIATELY TO PROHIBIT RESIDUES OF THAT POISON ON RAW AGRICULTURAL COMMODITIES

A. The Secretary must Prohibit Residues of Cancer-Producing Substances on Raw Agricultural Commodities

1. *The Anticancer Principle and Its Effect*

Congress entrusted responsibility for effectuating the purposes of the Food, Drug and Cosmetic Act to the Secretary of Health, Education, and Welfare; there is one area, however, in which the Secretary is given no discretion: he may not permit residues of cancer-producing substances on foods and in food products.

This principle, the so-called Delaney anticancer principle, was first explicitly included in the Act in 1958 as part of the food additives provision:

> *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, * * * [Section 409(c)(3)(A), 21 U.S.C. 348(c)(3)(A).][11]

The inclusion of that nondiscretionary language was a direct outgrowth of the world-wide concern that had been focused on the cancer problem in 1956 and 1957. The 1956 symposium of the International Union Against Cancer, which included cancer experts from some fifty countries, had reached the conclusion "that repeated exposure to even a minute dose of a cancer-producing agent constitutes a serious health hazard."[12] This finding was corroborated by scientists at the National Cancer Institute.[13]

Enactment of the Delaney anticancer clause followed as a reaction to the unchallenged scientific conclusion that no one knows how to establish safe tolerances for carcinogens. As stated by Secretary Flemming during his testimony on the color additives amendment of 1960:

> The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for man a safe tolerance for a cancer-producing agent. Until cancer research makes a

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[11] Substantially identical language was included in the color additives Section enacted in 1960 (Section 706(b) (5) (B), 21 U.S.C. 376(b) (5)(B), Supplement pp. 14-15. In 1962 the Delaney proviso of both the food and color additives sections was amended to permit the use of an additive as an ingredient of feed if it will neither adversely affect the animal nor will be found in any edible portion of the animal after slaughter nor in any food from the living animal. P.L. 87-781, 76 Stat. 785.

[12] 106 Cong. Rec. 14350, see also *Hearings*, p. 108.

[13] 106 Cong. Rec. 14350.

> breakthrough at this point, there simply is no scientific basis on which judgment or discretion could be exercised in tolerating a small amount of a known carcinogenic color or food additive. So long as the outstanding experts in the National Cancer Institute and the Food and Drug Administration tell us that they do not know how to establish with any assurance at all a safe dose in man's food for a cancer-producing substance, the principle in the anticancer clause is sound. [106 Cong. Rec. 14350.][14]

The statutory reference point was made a finding of carcinogensis either in humans *or* animals for the obvious reason that protective action should not be withheld until a chemical, although known to be cancer-producing in test animals, is established to have similar potentialities in humans. In fact, the Congress had been advised, in a report submitted to it by the National Cancer Institute, that "[i]f a substance is shown by adequate tests to be carcinogenic for one mammalian species, it is probable that it is carcinogenic for many, but not necessarily for all, other, although quantitative differences between species may be marked."[15]

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[14]This rationale was emphasized repeatedly by Secretary Flemming (*Hearings*, p. 61):

> The preponderance of scientific evidence clearly dictates our position: Our advocacy of the anticancer proviso in the proposed color additives amendment is based on the simple fact that no one knows how to set a safe tolerance for substances in human foods when those substances are known to cause cancer when added to the diet of animals. I should like to underline again one statement in particular which I read earlier from the summary of Dr. Mider's review of the role of certain chemical and physical agents in relation to cancer. It is this:
>
> *No one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop.*
>
> This is why we have no hesitancy in advocating the inclusion of the anticancer clause.

See also, *Hearings*, pp. 44, 61-62, 74, 87, 94-95, 501 and 507.

[15]*Hearings*, p. 53, from the report on "The Role of Certain Chemicals and Physical Agents in the Causation of Cancers" prepared by

Thus, once it is shown that a chemical or additive is a carcinogen in any strain of test animal no element of discretion remains; the Secretary must prohibit its use where there is a possibility that use would result in the presence of residues in food. This is not only the clear import of the statute and of its legislative history,[16] it has been the consistent construction given by the Secretary and by the only reviewing court that has considered the language.[17]

Secretary Flemming left no doubt as to how he construed the Delaney anticancer clause:

> [The anticancer clause] allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.
>
> * * *
>
> And under our basic policy, as well as under the Delaney clause, we have said that where those tests show that a substance will induce cancer when included in the diet of a test animal, that it will be banned. It cannot be used under those conditions. This is our interpretation of the Delaney amendment, and it is our conviction as to sound public policy.
>
> * * *

G. Burroughs Mider, M.D., Associate Director in Charge of Research, National Cancer Institute, National Institutes of Health, Public Health Service, Department of Health, Education and Welfare, quoting from the report of the Subcommittee on Carcinogenesis to the Food Protection Committee, Food and Nutrition Board, National Academy of Sciences - National Research Council.

[16] See 106 Cong. Rec. 14358, and Senate Report No. 2422, 85th Cong., 2d Sess., 1958 U.S. Code Cong. & Adm. News 5300, 5309-5310.

[17] *Bell v. Goddard*, 366 F.2d 177 (C.A. 6, 1966), discussed *infra*, p. 15.

> Now, if these tests show that these substances have induced cancer when ingested by these animals—and, as I said earlier, this question of whether they do or do not show is a matter for scientific determination and the exercise of scientific judgment—but if they show that they have induced cancer when included in the diet of one or both of these animals, then under the law we must ban the use of that particular substance.[18]

It was in full recognition of this contemporaneous administrative construction that the Congress reaffirmed its dedication to the Delaney principle by including it in the color additives amendment of 1960.[19]

Finally, the Sixth Circuit construed the Delaney clause as "generally intended to prohibit the use of any additive which under any conditions induce cancer in any strain of test animal." *Bell* v. *Goddard*, 366 F.2d 177, 181 (1966). In response to the argument that the per capita consumption of the chemical under attack—diethylstilbestrol, an estrogen additive used to produce juicier and fatter caponettes—was insignificant and that we are naturally exposed to estrogens, the Court said (366 F.2d at 182):

> [t]he answer to the petitioner's contentions in great part is that DES is a carcinogen. The record shows that DES is definitely a cause of cancer in animals, at least an inciter of incipient cancer in man, and possibly a cause of cancer in man. The record also shows that it may take many years, as much as the greater part of a lifespan, for a carcinogen to pro-

[18] *Hearings*, pp. 501, 514 and 517.

[19] Section 706(b)(5)(B), 21 U.S.C. 376(b)(5)(B).

Most recently the Mrak Commission, recognizing that "[t]he effect of the Delaney clause is to require removal from interstate commerce of any food which contains analytically detectable amounts of a food additive shown to be capable of inducing cancer in experimental animals," recommended modification of the language to permit the Secretary some area of discretion (App. B-4).

> duce a detectable cancer, and that the quantity of DES which is required to cause a cancer is presently unknown. All that is positively known is that there is a definite connection between DES and cancer. Furthermore, it was shown that prolonged exposure to even small amounts of carcinogenic substances is more dangerous than short term exposure to the same or even larger quantities.

2. *The Anticancer Principle is Fully Applicable to Pesticide-Chemicals*

As we have shown, the Delaney anticancer principle requires the Secretary to take whatever action is necessary to preclude the addition to food products of additives that are found to induce cancer when ingested by man or animal. We now show that that principle is fully applicable to pesticide-chemicals.

As is true of the Act generally, protection of the public health was an overriding objective sought to be realized by Congress when it enacted the pesticide provision. As stated in both the House and Senate Reports and by the floor leader in the House:

> A primary objective in drafting the bill was to develop legislation that would provide for prompt administrative action to permit effective use of pesticide chemicals without hazard to the public health; legislation that would be safe for consumers and practical for producers.[20]

Hence, in exercising his authority under the provision the Secretary is to consider "the overall effect the pesticide chemical may have in consumers' diets."[21] The Congress emphasized that:

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[20] House Report No. 1385, 83rd Cong., 2d Sess., p. 2; Senate Report No. 1635, 83rd Cong., 2d Sess., 1954 U.S. Code Cong. & Admin. News, p. 2627; 100 Cong. Rec. 9726.

[21] House Report No. 1385, *supra*, fn. 20, p. 3; Senate Report No. 1635, *supra*, fn. 20, p. 2628. See also House Report No. 1385, p. 8 and Senate Report No. 1635, p. 2632.

> Before any pesticide-chemical residue may remain in or on a raw agricultural commodity, scientific data must be presented to show that the pesticide-chemical residue is safe from the standpoint of the food consumer. The burden is on the person proposing the tolerance or exemption to establish the safety of such pesticide-chemical residue.[22]

Finally, the Congress made it clear that the tolerances were to be established by focusing on the particular pesticide-chemical "rather than with reference to the formulated or finished product itself. For example, in a finished product containing DDT a tolerance under this bill would be established for DDT rather than for the finished product itself."[23]

a. The Secretary, by contemporaneous administrative construction, has construed the Delaney principle as being fully applicable to the pesticide provision

It has long been recognized that "[a]dministrative practice, consistent and generally unchallenged, will not be overturned except for very cogent reasons [and that this] practice has peculiar weight when it involves a contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion * * *". *Norwegian Nitrogen Co.* v. *United States*, 288 U.S. 294, 315. As we show, the person "charged with the responsibility of setting" in motion the machinery of the Food, Drug and Cosmetic Act not only construed the Delaney principle as applying fully to the pesticide provision, he so told the Congress. Indeed, the Congress was advised that even if an anticancer policy had not been stated, the Secretary would nevertheless read the Act as if it were included. The Congress, apprised of this contemporaneous administrative construction, tacitly endorsed it.

[22]House Report No. 1385, *supra*, fn. 20, p. 5; Senate Report No. 1635, *supra*, fn. 20, p. 2629.

[23]House Report No. 1385, *supra*, fn. 20, p. 7; Senate Report No. 1635, *supra*, fn. 20, p. 2631.

The anticancer principle was first inserted in the Food Additives amendment enacted on September 6, 1958. By November 9, 1959, the Secretary already had construed its requirements as applying to pesticide-chemicals and, indeed, had relied upon it in ordering the destruction of raw agricultural commodities that contained residues of a pesticide-chemical which had been found to be capable of inducing cancer in test animals. The pesticide-chemical was aminotriazole, the raw agricultural commodities were cranberries. In stopping the sale of cranberries that were found to have residues of aminotriazole "which causes cancer in the thyroid of rats when it is contained in their diet," Secretary Flemming stated:

> Because of the implications of this incident in its relation to the safety of our food supply, I am prompted to make the following additional comment.
>
> As the cranberry episode illustrates, the Food and Drug Administration has declined to set any tolerance for any amount of a chemical in foods if the chemical produces cancer when fed to test animals. This principle is set down in the Food Additives Amendment, enacted last year, in a specific provision prohibiting the Food and Drug Administration from setting any tolerance for any such chemical. Even though the earlier Pesticide Amendment, which is applicable to the cranberries, does not contain such a specific prohibition, the same principle has been applied.
>
> The application of this principle is necessary in our opinion because while in theory there may be a minute quantity of a carcinogen which is safe in foods, in actuality our scientists do not know whether this is true or how to establish a safe tolerance.
>
> Therefore, we would oppose any attempt to take the cancer clause out of the Food Additives Amendment, and we will support the inclusion of such a

> clause in the color bill which is now before the Congress.[24]

Five days later, in issuing his third directive that contaminated cranberries be seized, Secretary Flemming said:

> Seizure action is being initiated on the basis that the berries were shipped illegally in interstate commerce since no tolerance for aminotriazole in foods has been established. Refusal by the Food and Drug Administration to set a tolerance for this chemical is in accordance with the Department's policy not to permit the use of chemicals in food when it is established that they cause cancer in animals or in man, a policy incorporated by Congress in the Food Additive Amendment to the Food, Drug and Cosmetic Act.[25]

On November 16, 1959, the Secretary expanded on the rationale underlying his actions:

> Refusal on the part of the Food and Drug Administration to permit the inclusion of any quantities of aminotriazole in food is based on the Department's policy of refusing to permit the use of chemicals in food when it is established that they cause cancer in animals or man. Research has established the fact that the weed killer, aminotriazole, causes cancer in the thyroid of rats when it is contained in their diet. The basic laws under which the Food and Drug Administration operate provide authority for the institution of such a policy.
>
> This policy, however, was actually looked at and considered by the Congress when in 1958 it included specific language in the Food Additive Amendment to the Food, Drug and Cosmetic Act.
>
> The provision states that "no additive shall be deemed safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests

[24] HEW, News Release, November 9, 1959.

[25] HEW, News Release, November 14, 1959.

> which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."
>
> In such circumstances, the Food and Drug Administration is prohibited from issuing regulations setting tolerances for the additive, and shipment of foods containing any amount of such additive in interstate commerce is therefore illegal.[26]

And on November 18, 1959, the Secretary not only reaffirmed that it was Departmental policy to apply the requirements of the Delaney anticancer principle to pesticide-chemicals, he also noted that he had so advised the Congress:

> I have called this conference for the purpose of considering a plan to be submitted by representatives of the cranberry industry designed to separate contaminated cranberries from those that are not contaminated.
>
> The shipment in interstate commerce of cranberries containing residues of aminotriazole is in violation of the Food, Drug, and Cosmetic Act.
>
> Refusal on the part of the Food and Drug Administration to permit the inclusion of any quantities of aminotriazole in food is based on the Department's policy of prohibiting as unsafe the use of chemicals in food when it is established that they cause cancer in animals or man. Research has established the fact that the weed killer, aminotriazole, causes cancer in the thyroid of rats when it is contained in their diet.
>
> It is the Department's position that because such a chemical is unsafe, we cannot issue a regulation setting a tolerance for it when it causes cancer in man or animal. Shipment of foods containing any amount of such a chemical in interstate commerce is therefore illegal.
>
> This policy is basic in our food and drug law, and it was spelled out in the law itself when Congress re-

[26] HEW, News Release, November 16, 1959.

cently passed the Food Additives Amendment. This included the following provision:

[Delaney Amendment set out]

In endorsing this language, we told Congress this policy was already in force under the pesticide chemicals law without the above-quoted language.[27]

This statutory construction was discussed in detail by the Secretary when he testified on the 1960 color additives amendment,[28] with the following colloquy taking place:

The CHAIRMAN. Mr. Younger.

Mr. YOUNGER. Yes, Mr. Chairman. Mr. Secretary, as regards the question of applying the test to any of the substances used in insecticides, or additives, have all of them been tested as to cancer?

Secretary FLEMMING. Mr. Congressman, and Mr. Chairman, taking the pesticides side of the amendment first, if I may do so—

Mr. YOUNGER. Yes.

Secretary FLEMMING. About 110 pesticides have been cleared, authorized, or certified as safe by the Food and Drug Administration. That means, of course, that that authorization includes the question of whether or not they are carcinogenic, or whether or not they do induce cancer.[29]

Furthermore, in a subsequent letter to Chairman Oren Harris of the House Committee on Interstate and Foreign Commerce, the Secretary again emphasized that

According to advice of our scientists, the principle of the above-quoted anticancer (Delaney) proviso of the Food Additives Amendment reflects, basically, the current state of scientific knowledge, and we would therefore, except as noted below, feel con-

[27] Statement of Arthur S. Flemming, November 18, 1959.

[28] *Hearings*, pp. 63-69, 89-90.

[29] *Hearings*, p. 75.

> strained to apply the same principle even in the absence of this proviso, and we do in fact apply it in the administration of the Pesticide Chemicals Amendment which does not contain the proviso.[30]

It is also of significance that in the regulations promulgated in implementation of the pesticide provision, only four specific reasons are detailed as examples of when it may be appropriate to establish a zero tolerance for the residues of a chemical. Among the reasons singled out for such emphasis is where (21 CFR 120.5):

> (b) The chemical is carcinogenic to or has other alarming physiological effects upon one or more of the species of the test animals used, when fed in the diet of such animals.

Moreover, the Secretary has emphasized that he would feel compelled to apply the anticancer principle even if it had not been expressly included in the Act. Senator Dirksen summarized the Secretary's position as follows (106 Cong. Rec. 15381):

> Mr. President, this matter has been of considerable interest to me. I have discussed it with the Secretary of Health, Education, and Welfare. He says that even if the Delaney amendment were deleted from the legislation, they would still have to apply that general principle, and that they do apply it on the advice of the National Institutes of Health.[31]

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[30] House Report No. 1761, 86th Cong., 2d Sess., 1960 U.S. Code Cong. & Adm. News, p. 2936.

It is interesting to note that the Department of Agriculture concurred in the conclusion that the requirements of the Delaney anticancer principle should be read into the pesticide provision. See *Hearings*, pp. 379 and 384-385.

[31] Similar characterizations of the Secretary's position were offered in the House by Chairman Harris (106 Cong. Rec. 14359 and 14362):

> The Secretary further stated that even if the Delaney clause is deleted from the bill, he believes that he has the authority to apply the policy that is reflected in that clause but he urged the Congress to join with the executive branch

The Secretary reached this conclusion in view of the overriding consumer protection objective of the Act and the inability to fix safe levels of carcinogens:

> As long as the preponderance of scientific evidence is in that particular direction, then I say that the policy incorporated in the Delaney amendment is a sound policy and one that we should follow.
>
> Whenever we establish the fact that a substance induces cancer when included in the diet of an animal, we are going to bar its use as far as it being included in the diet of man is concerned; that is, we are going to do everything we can under our existing law to achieve that objective.[32]
>
> * * *
>
> I want to emphasize the statement I made on January 26 that the Food, Drug and Cosmetic Act, as it now stands, will be enforced to prohibit the addition of cancer-producing substances to food unless a law should be passed directing us to follow another course of action.

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in giving added assurance to the public by including the anti-cancer clause in the proposed color additives legislation.

* * *

It is true that the Secretary of Health, Education, and Welfare did say if we did not have the Delaney clause in the bill - and I here want to join others in complimenting the gentlemen from New York [Mr. Delaney] for his consistent and determined effort toward this great problem - he would administer the law the same as if the Delaney clause had been written into it. The Secretary did have this provision in the bill when he sent it up to the Congress and asked me to introduce it. The Secretary testified he thought it should remain in the bill because he did not believe that he as Secretary or any administrator at this time should have the authority to make a determination permitting the use of any substance known to be cancer producing.

See also 106 Cong. Rec. 14358 and House Report 1761, 86th Cong., 2d Sess., 1960 U.S. Code Cong. & Adm. News, pp. 2932-2933.

[32] *Hearings*, pp. 95-96.

> Even though we have this authority in the law, we urge the Congress to join with the executive branch to give added assurance to the consuming public by directing the anticancer clause in the proposed color-additives amendment.[33]
>
> * * *
>
> As I indicated in my testimony, with or without a Delaney amendment on the food additives, with or without a Delaney amendment on the color additives, this is the policy that we would follow under the basic authority that has been conferred on us by Congress.
>
> We know of no other way of discharging that authority in a manner that would be fair to the consumer.[34]
>
> * * *

b. Congress intended for the Delaney principle to apply to the Food, Drug and Cosmetic Act generally, including the pesticide provision

As we have shown, Congress was well apprised of the fact that the Secretary was applying the Delaney anticancer principle to the pesticide provision and tacitly approved of that construction of the Act when it passed the color additives amendment. We now show that Congress itself considered the explicit statement of the Delaney principle unnecessary, rejected efforts to weaken the Act's built-in anticancer bias, and intended for the pesticide and food and color additives sections to be similarly construed.

Perhaps the most striking aspect of the legislative history of the first Delaney amendment is that the Committees of both the House and the Senate with responsibility for the Act, thought the amendment unnecessary; that is, considered it implicit in the general language of the Act. Congressman Oren Harris, Chairman of the Committee on Interstate and

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[33] *Hearings*, p. 501.

[34] *Hearings*, p. 506. See also, *Hearings*, pp. 61-63, 74, 508, 513, 524-526.

Foreign Commerce, explained the Committee's action as follows (104 Cong. Rec. 17414, emphasis added):

> Subsequently to the reporting of the bill, as amended in the full committee, the committee adopted unanimously a further amendment to the amendment. This amendment was suggested by Mr. DELANEY who over the years since he was the chairman of a Select Committee to Investigate the Use of Chemicals in Food and Cosmetics, has expressed his deep and abiding interest in this subject. *While the Committee felt that the bill as reported by the committee includes the matter covered by the Delaney amendment in the general language contained in the bill, there was no objection to the addition of the amendment suggested by Mr. DELANEY.* This amendment would be inserted on page 24, line 16 of the bill H.R. 13254, as reported; * * *

The report of the Senate Committee on Labor and Public Welfare is even more emphatic on this point (emphasis added):

> Two amendments made by your committee to the bill as passed by the House are explained below. We would like, in addition, to call attention to the fact that the Committee on Interstate and Foreign Commerce of the House of Representatives, before bringing the bill to a vote in the House, decided to add to its previously approved bill the provision which appears on page 8 of the House-passed bill (lines 10 to 15) and reads as follows:
>
> [Delaney anticancer clause set out]
>
> Your committee, which has the responsibility in the Senate of considering all legislation primarily relating to the health of our people, is well aware and thoroughly approving of the vast amount of time and energy which Congressman Delaney, author of that amendment, has devoted to the fight against cancer and to our attempts to find its cause and cure. *We have no objections to that amendment whatsoever, but we would point out that in our opinion it is the intent and purpose of this bill, even without that*

> *amendment, to assure our people that nothing shall be added to the foods they eat which can reasonably be expected to produce any type of illness in humans or animals.* We applaud Congressman Delaney for having taken this, as he has every other opportunity, to focus our attention on the cancer-producing potentialities of various substances, but we want the record to show that in our opinion the bill is aimed at preventing the addition to the foods our people eat of any substances the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability. *In short, we believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administrator.*[35]

Thereafter in 1960 Congress turned aside efforts to temper the impact of the anticancer principle: specifically, to make carcinogenicity just another factor to be considered by the Secretary. Chairman Harris explained why the House Committee rejected these efforts (106 Cong. Rec. 14359):

> The [National Academy of Sciences] panel discussed in considerable detail the scientific problems that confront us in connection with determination of the cancer-producing potentials of chemicals. They pointed out the difficulties of designing and conducting an experiment to determine whether a substance is a cancer producer for man and the difficulties in evaluating the test data after they are obtained.
>
> Some of the panel members have suggested that despite these difficulties, in extraordinary cases, the Secretary of Health, Education, and Welfare should have the authority to decide that a minute amount of a cancer-producing chemical may be added to man's food after a group of scientists consider all the facts and conclude that the quantity to be tolerated is probably without hazard.
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> * * *

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[35] Senate Report No. 2422, 85th Cong., 2d Sess., 1958 U.S. Code Cong. & Adm. News, pp. 5309-5310.

> In view of the uncertainty surrounding the determination of safe tolerances for carcinogens, the committee decided that the Delaney anticancer provision in the reported bill should be retained without change.

Finally, even had Congress not emphasized the pervasive nature of the anticancer prohibition, it intended for the pesticide, and food and color additives provisions to be similarly construed. Each of those provisions have the same fundamental purpose: safeguarding the public health by protecting the consumer.[36] Further, each was an outgrowth of the investigation and findings of the Select Committee to Investigate the Use of Chemicals in Food Products.[37] It was the apparent intent of the Select Committee to initiate substantially parallel legislation covering each of those areas.[38] The absence of the anticancer clause in the pesticide provision is explained by the fact that it had been enacted two years before disclosure of the cancer findings which prompted the Delaney amendment. (See *supra*, p. 12). And there was no reason for Congress to amend the pesticide provision: first, Congress did not consider the anticancer clause necessary (see *supra*, pp. 25-26) and second, it was fully apprised of the Secretary's determination—as a matter of law—to apply the anticancer principle no less rigorously to pesticide-chemicals (see *supra*, p. 17).[39]

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[36] *Pesticides:* House Report No. 1385, *supra*, fn. 20, pp. 2, 3, 5 and 7; Senate Report No. 1635, *supra*, fn. 20, pp. 2627-2629 and 2632; 100 Cong. Rec. 9726. *Food Additives:* House Report No. 2284, 85th Cong., 2d Sess., pp. 1, 4 and 5; Senate Report No. 2422, *supra*, fn. 16, p. 5301; 104 Cong. Rec. at 17413, 17416, 17418-17420. *Color Additives:* 106 Cong. Rec. at 14350 and 14358.

[37] *Pesticides:* House Report No. 1385, *supra*, fn. 20, p. 4; Senate Report No. 1635, *supra*, fn. 20, p. 2628; *Food Additives:* House Report No. 2284, *supra*, fn. 36, p. 2; *Color Additives:* 106 Cong. Rec. 14358; *Hearings*, p. 107.

[38] House Report No. 2356, 82nd Cong., 2d Sess., pp. 26 and 27. See, also, *United States* v. *Bodine Produce Co.*, 206 F. Supp. 201, 206-207 (Ariz., 1962).

[39] It is not without interest that industry groups did not object either to the explicit inclusion of the anticancer clause in the color

> *amendment, to assure our people that nothing shall be added to the foods they eat which can reasonably be expected to produce any type of illness in humans or animals.* We applaud Congressman Delaney for having taken this, as he has every other opportunity, to focus our attention on the cancer-producing potentialities of various substances, but we want the record to show that in our opinion the bill is aimed at preventing the addition to the foods our people eat of any substances the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability. *In short, we believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administrator.*[35]

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>
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[36] *Pesticides:* House Report No. 1385, *supra*, fn. 20, pp. 2, 3, 5 and 7; Senate Report No. 1635, *supra*, fn. 20, pp. 2627-2629 and 2632; 100 Cong. Rec. 9726. *Food Additives:* House Report No. 2284, 85th Cong., 2d Sess., pp. 1, 4 and 5; Senate Report No. 2422, *supra*, fn. 16, p. 5301; 104 Cong. Rec. at 17413, 17416, 17418-17420. *Color Additives:* 106 Cong. Rec. at 14350 and 14358.

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[39] It is not without interest that industry groups did not object either to the explicit inclusion of the anticancer clause in the color

In *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, a unanimous court upheld the Secretary's decision to decertify a coal-tar color, which had been certified for almost fifteen years, because evidence before him indicated that the color, when included in the diets of rats in small dosages "was deleterious and often fatal, with liver damage and enlargement of the heart in evidence." 358 U.S. at 159. It is significant that the color additives provision had not yet been amended to include, explicitly, the anticancer principle. Yet the court agreed that it was appropriate for the Secretary to base his potential harm to humans finding on the results obtained from the testing of laboratory animals. See, also: *Certified Color Industry Committee, et al.* v. *Secretary*, 283 F.2d 622 (CA 2, 1960), where the court extended *Florida Citrus* to permit the Secretary to apply his revocation order to color batches previously certified.[40]

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additives provision or its implicit reading by the Secretary into the pesticide provision. *Hearings*, pp. 172, 182 and 183.

[40]That each of these provisions is to be similarly construed is also evident from the comments of Assistant Secretary of Commerce Elliot L. Richardson, on the inclusion of the first proposed anticancer clause (104 Cong. Rec. 17415):

> The widespread interest in cancer led to suggestion that the food additives legislation should mention the disease by name and forbid the approval of any substance that is found upon test to cause cancer in test animals. This Department is in complete accord with the intent of these suggestions - that no substance should be sanctioned for uses in food that might produce cancer in man. H.R. 13254, as approved by your committee, will accomplish this intent, since it specifically instructs the Secretary not to issue a regulation permitting use of an additive in food if a fair evaluation of the data before the Secretary fails to establish that the proposed use of the additive will be safe. The scientific tests that are adequate to establish the safety of an additive will give information about the tendency of an additive to produce cancer when it is present in food. Any indication that the additive may thus be carcinogenic would, under the terms of the bill, restrain the Secretary from approving the proposed use of the additive unless and until further testing shows to the point of reasonable certainty that the additive would not produce cancer and thus would be safe under the proposed conditions

B. The Record Establishes that DDT is a Carcinogen

As we have shown the Delaney anticancer principle pervades the entire Food, Drug and Cosmetic Act and applies with full force to its pesticide provision. That being the case it is incumbent upon the Secretary to establish, without delay, zero tolerances for the residues of any pesticide-chemical which is found capable of inducing cancer in man or in "any strain of test animal." *Bell* v. *Goddard*, *supra* at p. 181.

We now show that in light of the overwhelming and uncontroverted evidence of record which establishes the carcinogencity of DDT, it is incumbent upon the Secretary to take immediate action directed at securing the complete absence of DDT residues on raw agricultural commodities.

1. *The Evidence Presented to the Secretary by Petitioners Establishes that DDT is a Carcinogen*

In support of their contention that DDT is a carcinogen petitioners submitted three scientific studies. The most comprehensive was that recently completed by thirteen scientists working under the sponsorship of the National Cancer Institute, National Institutes of Health, Department of Health, Education, and Welfard—the so-called *Innes* report (App. A-14).[41] DDT was added to the diet of mice and compared with both positive and negative control groups (App. A-15). The frequency of tumors of the liver, lungs and lymphoid organs was four times greater in mice fed DDT than those in the negative control group (App. A-24). The carcinogenicity was clearly established because DDT caused cancer of the same kind and at approximately the same frequency as did

of use. This would afford good, strong public health protection.

[41] *Bioassay of Pesticides and Industrial Chemicals for Tumorigenicity in Mice: A Preliminary Note*, J. R. M. Innes, *et al.*, 42 Journal of the National Cancer Institute 1101 (June, 1969).

known cancer-causing agents, the positive controls (App. A-24, 26).

The National Cancer Institute study confirmed earlier evidence indicating the carcinogenicity of DDT. One study also submitted in support of the petition, a five generation study of mice, is particularly probative for it found carcinogenicity to result from prolonged exposure to low levels of DDT.[42] The mice were fed a dosage of DDT at a level which resulted in its accumulation in the fatty tissue of the experimental group in "the same order as the DDT level in the fatty tissue of the urban population" (App. A-29). It was found that the mice which had been subjected to the accumulation of low levels of DDT developed a substantially higher incidence of leukemia and of tumors than did the non-DDT mice (App. A-29).

Finally, petitioners submitted a study which is at least probative evidence that DDT may have carcinogenic effects in man.[43] In studies undertaken at the University of Miami School of Medicine, human victims of terminal cancer were found to contain more than twice the concentration of DDT residues in their fat as did victims of accidental death (App. A-34, 35). The accident victims were found to carry 9.7 parts per million in their fat, about average for Americans, while the cancer victims contained 20 to 25 parts per million (App. A-34-36).

2. *The Report of the Mrak Commission Corroborates Conclusively the Finding that DDT is a Carcinogen*

In rejecting the petition the Secretary acknowledged that he had relied in part on the findings of the Mrak Commission.

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[42] *Investigations on the Effects of Chronically Administered Small Amounts of DDT in Mice*, Kemeny and Tarian, 22 Experientia 748 (1966) (App. A-28).

[43] *Pesticide Concentrations in the Liver, Brain and Adipose Tissue of Terminal Hospital Patients*, J. L. Radomski, W. B. Deichmann, E. E. Clizer, 6 Food Cosmetics and Toxicology 209 (1948) (App. A-30).

However the findings of that Commission, rather than in any way detracting from the effect of the scientific evidence submitted by petitioners, supports fully the conclusion that DDT is a carcinogen.[44]

At the outset it should be noted that the Commission acknowledged the credibility of the *Innes* study (App. B-41), agreeing both with the propriety of using test "doses considerably higher than would be present in food" (App. B-37) and with the conclusion of the *Innes* group that evidence of increased tumorigenicity must be accepted as an index of potential carcinogenicity (App. B-36) since "(a) No adequately tested chemical has been found to produce only benign neoplasms and, (b) a substantial percentage of benign-appearing tumors in mice has been demonstrated ultimately to eventuate in cancer" (App. B-47).

The panel itself caterogized pesticide-chemicals according to their probable carcinogenesis (App. B-38). Of critical significance is the fact that DDT was included among the "compounds judged 'positive' for tumor induction on the basis of tests conducted adequately in one or more species, the results being significant at the 0.01 level" (App. B-40). Indeed, the panel acknowledged that "the observations of human experience have not been sufficient to eliminate the possibility that continued chronic exposure [to DDT] may slowly induce a low level of cancer in man" (App. B-41).

The Commission's Technical Panel on Carcinogenesis was particularly concerned about reducing residues in food because it found that (App. B34):

> The presence of carcinogenic substances (of both synthetic and natural origin) in food might be a significant factor in the occurrence of what is

[44] Indeed, the Commission stated that "the evidence for the carcinogenicity of DDT in experimental animals is impressive and the Panel takes no exception to the conclusions as to DDT recorded in the JNCI report of the National Cancer Institute study." (App. B-41).

commonly referred to as "spontaneous" cancer in man and animals. * * *[45]

C. The Secretary Has Utterly Failed to Comply With the Act

It remains only to apply the principle of the Delaney clause to the evidence of the carcinogenicity of DDT. We submit that there is no way in which the anticancer principle can be applied, short of its complete obliteration, without reaching the conclusion that the Secretary is under a statutory mandate to take whatever action is necessary to achieve the elimination of DDT residues from raw agricultural commodities.

But what has the Secretary done; he has responded with grandiose assurances that he will, sometime in the future, consult with the Secretaries of Agriculture and Interior "on the environmental contamination aspects of pesticide registrations" and he has "agreed that HEW should review established tolerance levels of specific pesticides in food and drinking water." This is the sum and substance of the Secretary's response; assurances of concern coupled with the postponement of action. These, declared the Secretary in his rejection of petitioners' request for immediate action, "are the most reasonable steps that [he] should be tak[ing] at this time" (App. A-98).

What the Secretary ignores, however, is that the Delaney anticancer principle permits no equivocation; it does not ask for assurances and promises but rather for action and immediate action at that. This is where the Secretary has completely failed to discharge his responsibility. Stripped of rheteric he has done nothing to protect the public from the continued ingestion of the carcinogen DDT. To be sure it is the Secretary of Agriculture that has the authority to suspend and cancel the registration of pesticides. But the Secretary of Health, Education, and Welfare cannot hide

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[45] Earlier in the Report it is stated that since human exposure to pesticides is greatest through foods; "so far as the health of the general population is concerned, the greatest emphasis on pesticide control should be on reducing the concentrations in food" (App. B-7).

behind that dichotomy of authority; he has his own responsibilities and they require taking all actions necessary to effect the immediate cessation of the use of DDT.

The Secretary's preoccupation with possible adverse economic effects on industry is misplaced. The clear import of the Delaney amendment is that when the conflict is between possible economic disruption and the ingestion of a carcinogen, protection of the public health, and not the enhancement of private gain, is always to win out. Certainly this is made clear in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, where the Supreme Court rejected the contention that the Secretary was to establish a tolerance for a color (which was found not to be harmless) because its use was an economic necessity. It is noteworthy that unlike DDT the additive there at issue is not a carcinogen.

It is particularly imperative that the Secretary move with all possible expedition in the case of DDT. First, the studies of *Radomski, et al.* submitted by petitioners (App. A-30) are at least circumstantial evidence that DDT may be carcinogenic not only in test animals but in man as well; the Mrak Commission itself raised a serious question along these lines (App. B-41). Second, the chemical stability of DDT, with a probable "half-life" of 10 to 15 years, makes it imperative that its usage be prohibited immediately. Lastly, each member of the public, once having been warned of the potential dangers of most food additives can voluntarily stop their further ingestion. In the case of DDT no element of choice exists. Like it or not each of us is forced to ingest DDT regularly included as an additive to the food we eat.

Even if it were permissible for the Secretary to defer immediate action directed at the withdrawal of a pesticide carcinogen the continued use of which is necessary for public health and food production purposes, deferral of action in the case of DDT could not be justified. The Mrak Commission found that (App. B-5):

> It is reported by well informed scientists that as far as insect vectors of disease are concerned there are none known which are normally susceptible to DDT that cannot be controlled with a substitute.

* * *

> * * * Although DDT is still involved in some of the international food production programs sponsored by U.S. agencies, there is a feeling that a withdrawal or systematic reduction of DDT would have a minimum effect.[46]

II

PETITIONERS PRESENTED "REASONABLE GROUNDS" IN SUPPORT OF THEIR PETITION; ACCORDINGLY, IT WAS INCUMBENT UPON THE SECRETARY TO AT LEAST PUBLISH THEIR PROPOSAL IN THE *FEDERAL REGISTER* THEREBY INITIATING THE ADMINISTRATIVE PROCEDURES

In response to the petition, W. B. Rankin, Deputy Commissioner, Food and Drug Administration, advised petitioners that it was "being processed as provided by 21 CFR 120.32" (App. A-86). That regulation provides that "an interested person furnishing reasonable grounds therefor, may propose * * * repealing a tolerance for a pesticide chemical on raw agricultural commodities * * *." It defines "reasonable grounds" as including "an explanation showing wherein the person has a substantial interest in such tolerance * * * and an assertion of facts (supported by data if available) showing * * * that new data are available as to toxicity of the chemical * * *." Subsequently, Herbert L. Ley, Jr., M.D., Commissioner of Food and Drugs, by letter of December 8, 1969, advised petitioners of the Department's determination that "a proposal based on [their] petition is not being published" (App. A-98). After referring to the persistence of DDT, Commissioner Ley found that "in the absence of a showing that establishing the zero tolerances you request would be practical, we find that you have not presented reasonable grounds to support the proposed action" (App. A-98).

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[46] See also App. B-6, 25. This is because of the fact that there are many alternatives to DDT (App. B-5, 7), alternatives "that do not have the damaging side effects on the environment that DDT exhibits" (App. B-6).

The effect of this determination was to deprive petitioners not only to the benefits of *Federal Register* publication, but to deny to them the entire administrative machinery provided for in the Food, Drug and Cosmetic Act. While it is conceded that the fact that there is widespread environmental contamination complicates the problem for the Secretary, it is ludicrous to thereby suggest that the Secretary need do little more than bemoan the magnitude of the problem. Instead, what is called for is full utilization of the administrative processes for the collection and distillation of all possible solutions.

The procedures provided for in 21 CFR 120.32 have a dual purpose. First, to assist the Secretary in the discharge of his statutory responsibilities by invoking a dialogue as to the dangers of a particular pesticide and second, to assist the Secretary by focusing on the solutions which are available to him to meet a recognized danger. In the case of DDT the dangers are uncontroverted; it is the solution which is at issue. The Secretary, by his own concession, does not himself know how to solve the DDT problem. The purpose of 21 CFR 120.32 is to permit the public generally to lend its assistance with the hope of broadening the Secretary's awareness as to what can be done.

Petitioners recognized the difficulty of the problem which confronts the Secretary (a problem which under the Delaney principle he cannot lawfully ignore) and in their supplemental filing of October 31, 1969 suggested a possible solution which would give effect to the anticancer mandate while not threatening confiscation of a major portion of our food supply—the immediate establishment of zero tolerances with exemption from seizure of any commodities that contain DDT residues that are a consequence of applications made prior to the effective date of the revised tolerances.

We do not suggest that this is the only procedure for effecting the required zero tolerance. We do contend that it is not a frivolous suggestion and that it should have suggested to the Secretary that had the proposal been

published in the *Federal Register* other solutions would have been forthcoming.[47] The real objective of public notice is, after all, to marshall information for the benefit of administrative agencies that may unfortunately be less than omniscient but nevertheless have to make judgments which can have a profound effect on our well-being. It is clear therefore, that petitioners[48] and the public generally were substantially prejudiced by the Secretary's refusal to notice the proposal.

There was no basis upon which the Secretary properly could conclude that petitioners had not presented "reasonable grounds" sufficient, at least, to initiate the administrative process.[49]

We have already shown that DDT is a carcinogen. We now show that wholly apart from its carcinogenic potentials DDT represents an imminent hazard to human health, if indeed, not to survival itself.[50]

> Man is an integral part of the living system which includes about 200,000 species in the United States. *Most of these are considered to be essential to the well-being of man.* Pesticides are now affecting individuals, populations, and communities of natural organisms. Some, especially the persistent insecticidal chemicals such as DDT, have reduced the reproduction and survival of nontarget species. (App. B-8, emphasis added).

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[47] The Mrak Commission itself offered an alternative proposal, the "stepwise lowering" of tolerances (App. B-4).

[48] It should be noted that no suggestion was made in Dr. Ley's letter that the petitioners were not "interested persons" or that they otherwise lacked standing to prosecute their petition.

[49] The Secretary's denial seems premised on a failure to establish reasonable grounds in support of the particular solution offered by petitioners; the regulation does not permit so restrictive a reading.

[50] A showing of carcinogenicity is, of course, not necessary to initiate a repeal proceeding.

That conclusion of the Mrak Commission is corroborated in frightening detail throughout its voluminous report. DDT residues are established nerve toxins and have acute effects on the central nervous system (App. B-21, 22, 25).[51] In addition, DDT residues are responsible for the induction of metabolizing enzymes in the liver, including in the liver of man (App. B-20, 24, 29),[52] thus "alter[ing] the susceptibility to drugs or other ehcmicals that are normally metabolized by these enzymes" (App. B-61), and generally causing liver damage (App. B-21, 22, 26, 28). And DDT concentrations in fat (it is accumulated in fatty tissue) may itself "constitute a health hazard". (App. B-27).[53]

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[51] The Commission specifically found that:

> The chlorinated hydrocarbon insecticides, especially DDT, have been known to act in the cerebellum, brainstem, spinal cord, and peripheral nerves * * * Thus the acute effects of these compounds appear to be scattered widely throughout the nervous system. Moreover, they have topical action on the nerve endings in the mucous membrane (Hayes, 1963) and may extend their action proximally on the nerve pathways as shown by various case reports, * * * (App. B-28).
>
> * * * *
>
> In animals, the earliest apparent effect of DDT poisoning is abnormal susceptibility to fear, with violent reaction to stimuli that normally would be unnoticed (Hayes, 1965). There is definite motor unrest and an increased frequency of spontaneous movements. A fine tremor appears and becomes constant, interfering with normal activity. As the nervous system involvement progresses, there are attacks of epileptiform tonoclonic convulsions. Death may result from ventricular fibrillation. (App. B-29)

[52] As stated by the Mrak Commission, "it is a sad comment on the dearth of knowledge of human physiology to point out that the threshold dose of DDT for induction of metabolizing enzymes in human liver is unknown." (App. B-20).

[53] The Mrak Commission goes on to acknowledge that "rapid mobilization of fat in nutritional deprivation may result in sufficiently high residual DDT levels to produce conventional toxicity * * * Such toxicity has actually been demonstrated for DDT in rats in laboratory experiments" (App. B-27).

Apart from these direct human health hazards from the exposure to DDT residues, such residues have a profound effect on the biosphere upon which man is dependent. For example, DDT and its residues interfere with the photosynthetic process (App. B-6, 15). The relationships between DDT residues and hazards to bird populations, by both direct mortality and reproductive failure, have been particularly well documented. (App. B-16). DDT causes carniverous birds, including birds of prey,[54] sea birds, and many other species, to lay eggs with abnormally thin shells. These eggs break prematurely resulting in sharply reduced reproductive success. Populations of these species have in many cases undergone catastrophic declines, in some cases approaching extinction. The decline in eggshell thickness occurred in the late 1940's, shortly after the large scale introduction of DDT into the world environment. Controlled feeding experiments with DDT and its metabolites have established the casual relationship between DDT residues, the production of eggs with abnormally thin shells, and greatly reduced reproductive success (App. B-17).

DDT inhibits reproduction in fish, with abnormal mortality of the fry following the contamination of the adult fish and their eggs. This has occured in several freshwater situations, with mortalities of 100 percent of the fry in some instances (App. B-16). Controlled experiments confirmed that DDT residues were the causative agents (*ibid.*). Many fish from other areas, including commercially important fish from marine waters, show concentrations of DDT residues in their tissues that approach those that caused this abnormal fry mortality. Important freshwater and marine fisheries are

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[54] This is a consequence of biological magnification which results in the concentration of DDT residues as you move up a food chain. ("Chemicals which are preferentially absorbed into living organisms and stored for extended period, as are DDT and its derivatives, may, therefore, be concentrated greatly up the food chain" (App. B-12)). This is particularly of concern to man who is of course, at the top of a food chain.

seriously threatened by present and anticpated future concentrations of DDT residues in the tissues of the fish.[55]

DDT residues do great damage to useful invertebrates of many species. Insect communities are frequently disrupted by the killing of beneficial predatory and parasitic insects, thereby aggravating the insect pest problem DDT was intended to control. DDT kills pollinating insects. It damages various crustaceans such as crabs and shrimp (App. B-16). Even the base of oceanic food chains, the phytoplankton, can have their photosynthetic activity reduced by a few parts per billion of DDT in the water (App. B-6, 15).

The indirect cost to society of this degradation reaches the incalculable (App. B-18). It is not at all surprising that the Mrak Commission, "after carefully reviewing all available information" (App. B-2):

> * * * concluded that there is adequate evidence concerning potential hazards to our environment and to man's health to require corrective action. Our Nation cannot afford to wait until the last piece of evidence has been submitted on the many issues related to pesticide usage. We must consider our present course of action in terms of future generations of Americans and the environment that they will live in.

These facts undoubtedly explain why the use of DDT on raw agricultural commodities is increasingly being prohibited by governmental authorities.[56]

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[55] It was DDT contamination of coho salmon that led to the establishment of the Mrak Commission.

[56] For example restrictive action has been ordered by the States of Arizona, California, Florida, Maryland, Michigan and Wisconsin, the Canadian federal government and several of the provinces, and by Sweden.

CONCLUSION

In light of the uncontroverted evidence that DDT is a carcinogen, this proceeding should be remanded to the Secretary with directions that he immediately take all action that is necessary to effect the elimination of that poison from raw agricultural commodities. Administrative proceedings conducted following remand should not be concerned with whether it is appropriate to continue, for any period of time, using DDT; rather, the Secretary should consider only the solution that should be implemented to afford the consuming public the greatest possible protection from continued exposure to that cancer-producing poison.

Respectfully submitted,

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SUPPLEMENT

The pertinent parts of the Food, Drug and Cosmetic Act. 52 Stat. 1040, as amended, 21 U.S.C. 301, *et seq.* are as follows:

TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Sec. 408 [346a]. (a) Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 402(a) unless–

(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Secretary of Health, Education and Welfare under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Secretary under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 402(a).

(b) The Secretary shall promulgage regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience

to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Secretary shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion of the Secretary of Agriculture as submitted with a certification of usefulness under subsection (l) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Secretary may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Secretary does not justify the establishment of a greater tolerance.

(c) The Secretary shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

(d) (1) Any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Secretary of Health, Education, and Welfare, a petition proposing the issuance of a regulation, establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of such economic poison, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

(A) the name, chemical identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Secretary upon request. Notices of the filing of such petition shall be published in general terms by the Secretary within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

(2) Within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (1) with respect to the pesticide chemical named in the petition, the Secretary of Health, Education, and Welfare shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Secretary within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness

by the Secretary of Agriculture under subsection (1), with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Secretary of Health, Education, and Welfare within such period otherwise deems such referral necessary, the Secretary of Health, Education, and Welfare shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal in the petition to the Secretary, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

(B) esempting the pesticide chemical from the necessity of a tolerance for such purposes

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection (e), may file objections thereto with the Secretary, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the peti-

tioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which even the Secretary shall specify in the order his findings as to such conditions.

(e) The Secretary may at any time, upon his own initiative or upon the request of any interested parson, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Secretary may by order publish a regulation based upon the proposal which shall become effective upon pub-

lication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Secretary shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary may, after giving due consideration to all data before him, including such reports, recommendations, underlying data and statement , by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).

(f) All data submitted to the Secretary or to an advisory committee in support of a petition under this section shall be considered confidential by the Secretary and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Secretary or by an advisory committee in the carrying out of their official duties under this section.

(g) Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Secretary otherwise deems such referral necessary, the Secretary shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while to serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedures to be followed by the committee.

(h) A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provision of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (g) in connection with the petition or proposal.

(i) (1) In a case of actual controversy as to the validity of of any order under subsection (d) (5), (e), or (l) any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60

days after entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d) (5) or (e), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisidiction to affirm, or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (1), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary of Agriculture, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary of Health, Education, and Welfare or the Secretary of Agriculture as the case may be, and to be adduced upon the hearing in such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary of Health, Education, and Welfare or the Sec-

retary of Agriculture, as the case may be, may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(j) The Secretary may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the use covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Secretary shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

(k) Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, in accordance with section 702(e), shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m).

(l) The Secretary of Agriculture, upon request of any person who has registered, or who has submitted an applica-

tion for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d) (1) with respect to a pesticide chemical which constitutes, or is an ingredient of, such economic poison, shall, within thrity days or within sixty days if upon notice prior to the termination of such thirty days the Secretary deems it necessary to postpone action for such period, on the basis of data before him, either–

(1) certify to the Secretary of Health, Education, and Welfare that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary of Agriculture to certify to the Secretary of Health, Education, and Welfare on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Secretary may by order make the certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Secretary shall by order make the certification as proposed with respect to such parts thereof as are requested. In the event a hearing is requested, the Secretary of Agriculture shall provide opportunity for a prompt hearing. The certification of the Secretary of Agriculture as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of

fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture exceed one hundred and sixty days. The Secretary shall submit to the Secretary of Health, Education, and Welfare with any certification of usefulness under this subsection an opinion based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying the provisions of this subsection.

(m) The Secretary of Health, Education, and Welfare shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

(n) The provisions of section 303(c) of the Federal Food, Drug and Cosmetic Act with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

(o) The Secretary of Health, Education, and Welfare shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Secretary, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) the acceptance of filing of a petition submitted under subsection (d); (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity

of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d)(5); or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i)(2). Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection.

This Act shall take effect upon the date of its enactment [July 22, 1954] except that with respect to pesticide chemicals for which tolerances or exemptions have not been established under section 408 of the Federal Food, Drug, and Cosmetic Act, the amendment to section 402(a) of such Act made by section 2 of this Act shall not be effective—

(1) for the period of one year following the date of the enactment of this Act; or

(2) for such additional period following such period of one year, but not extending beyond two years after the date of the enactment of this Act, as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period.

FOOD ADDITIVES

Unsafe Food Additives

Sec. 409 [348]. (a) A food addivite shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402(a), unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402(a).

* * *

Action on the Petition

(c)

* * *

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

* * *

LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

When Color Additives Deemed Unsafe

Sec. 706 [376]. (a) A Color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be unless—

(1) (A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

* * *

(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of addi-

tives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal: *Provided*, That clause (i) of this subparagraph (b) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

* * *

The pertinent parts of the administrative regulations promulgated in implementation of the Food, Drug and Cosmetic Act, 21 CFR Part 120, are as follows:

§ 120.5 Zero tolerances.

A zero tolerance means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined.

(b) The chemical is carcinogenic to or has other alarming physiological effects upon one or more of the species of the test animals used, when fed in the diet of such animals.

(c) The pesticide chemical is toxic, but is normally used at times when, or in such manner that, fruit, vegetables, or other raw agricultural commodities will not bear or contain it.

(d) All residue of the pesticide chemical is normally removed through good agricultural practice such as washing or brushing or through weathering or other changes in the chemical itself, prior to introduction of the raw agricultural commodity into interstate commerce.

* * *

§ 120.32 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner on his own initiative or on request from an interested person furnishing reasonable grounds therefor, may propose the issuance of a regulation amending or repealing a tolerance for a pesticide chemical on raw agricultural commodities or granting or repealing an exemption from tolerance for such chemical. Requests for such amendment or repeal shall be made in writing and accompanied by an advance deposit to cover fees as provided in § 120.33(d).

(b) Reasonable grounds shall include an explanation showing wherein the person has a substantial interest in such tolerance or exemption from tolerance and an assertion of facts (supported by data if available) showing that new uses for the pesticide chemical have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the application of the tolerance or exemption from tolerance may justify its amendment or repeal. Evidence that a person has registered or has submitted an application for the registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act will be regarded as evidence that he has a substantial interest in a tolerance or exemption from the requirement of a

tolerance for a pesticide chemical that consists in whole or in part of the economic poison. New data should be furnished in the form specified in § 120.7(b) for submitting petitions.

(c) The notice announcing the proposal to amend or repeal a regulation shall show whether the proposal was made on the initiative of the Commissioner or at the request of an interested person, naming such person. From this point the proceedings shall be the same as prescribed by section 408(e), beginning with the second sentence of that paragraph, and the regulations applicable to section 408(d), (e), (f), and (g).

* * *

§ 120.147 DDT; tolerances for residues.

Tolerances for residues of the insecticide DDT (a mixture of 1,1,1,-trichloro-2,2-bis(*p*-chlorophenyl)ethane and 1,1,1-trichloro-2-(*o*-chlorophenyl)–2-(*p*-chlorophenyl)ethane are established in or on raw agricultural commodities as follows:

50 parts per million in or on peppermint hay and spearmint hay, which are not to be used for feeding livestock.

20 parts per million in or on fresh hops. Any byproducts or refuse from such hops are not to be used for feeding livestock.

7 parts per million in or on apples, apricots, beans, beet greens, blueberries (huckleberries), cabbage, celery, collards, cranberries, cucumbers, eggplants; fat of meat from cattle, goats, hogs, horses, and sheep; grapes, kale, lettuce, mangoes, melons, mustard greens, nectarines, okra, onions, parsnip greens, peaches, pears, peas, peppers, pineapples, pumpkins, quinces, radish tops, rutabaga tops, spinach, squash, summer squash, sweetpotatoes (from postharvest use), Swiss chard, tomatoes, turnip greens.

4 parts per million in or on cottonseed.

3.5 parts per million in or on avocados, carrots, cherries, citrus fruits, the fresh vegetable sweet corn (determined on kernels plus cob after removing any husk present when marketed), papayas, plums (fresh prunes).

3.5 parts per million combined residues of DDT and toxaphene in or on soybeans (dry form), of which residues DDT shall not exceed 1.5 parts per million and toxaphene shall not exceed 2 parts per million.

1.5 parts per million in or on soybeans (dry form).

1 part per million in or on artichokes, asparagus, beets (roots), blackberries, boysenberries, broccoli, brussels sprouts, cauliflower, currants, dewberries, endive (escarole), gooseberries, guavas, kohlrabi, loganberries, mushrooms, parsnips (roots), peanuts, potatoes (determined after washing off any soil present when marketed), radishes (roots), raspberries, rutabagas (roots), strawberries, turnips (roots), youngberries. [33 F.R. 9396, June 27, 1968]

§ 120.147a DDT residues in corn forage, corn fodder, corn silage, corn stover, and sweet corn cannery waste; statement of policy and interpretation.

(a) Section 120.101(e)(4) of this chapter, promulgated on March 11, 1955, permitted a tolerance of 7 parts per million for residues of DDT in or on the fresh vegetable sweet corn. Because of a showing of the unsuitability of the tolerance level based on sweet corn as marketed, § 120.147 provides a tolerance of 3.5 parts per million of DDT in or on the fresh vegetable sweet corn (determined on kernels plus cob after removing any husk present when marketed). Residue studies have indicated that the application of DDT in any manner to the feed of dairy cows or to the dairy cows themselves results in residues of DDT in milk. No tolerance has been established to permit any residues of DDT in milk from feeding corn forage, corn fodder, corn silage, corn stover, or sweet corn cannery waste to dairy cows. When these items contain any amount of DDT, they are unsuitable as a feed for dairy cows and should not be represented, sold, or used for that purpose.

(b) A tolerance of 7 parts per million for residues of DDT in the fat of meat from cattle, goats, hogs, horses, and sheep has been established in § 120.147. Animals that consume

corn forage, corn fodder, corn silage, corn stover, or sweet corn cannery waste containing DDT may accumulate considerably more of the chemical in their fat than is present in the feed itself, and a long time may be required on a diet free of DDT to reduce excessive levels of DDT to the tolerance level. Unless the person who raises meat animals is in a position to determine the magnitude of DDT residues in these corn feed products and to insure that the conditions of feeding are such that the residues in meat from such animals will be within the established tolerance, these products from DDT-treated corn should not be used in the feeding of meat animals.

(See also § 121.226 of this chapter.)

[27 F.R. 12092, Dec. 6, 1962, as amended at 32 F.R. 4059, Mar. 15, 1967]

§ 120.147b DDT residues in applie pomace.

(a) Investigations by the Food and Drug Administration show that apple pomace containing substantial amounts of DDT has been used as feed for dairy and meat animals. Section 409 of the act would render illegal any apple pomace for animal feeding that contains DDT in excess of the 7 parts per million fixed for apples by § 120.147. It has been established that the feeding of apple pomace containing DDT will contribute residues of DDT to the fat of meat animals and to milk of dairy animals.

(b) There is no tolerance for DDT in milk to provide for residues that may occur from feeding apple pomace which contains DDT to dairy animals. Apple pomace containing DDT should not be fed to dairy animals, since it has been established that the ingestion by them of even small amounts of DDT results in contamination of the milk with this pesticide. Apple pomace containing any amount of DDT is unsuitable as a feed for an ingredient of mixed feeds for dairy animals and should not be represented, sold, or used for that purpose.

(c) There is an established legal tolerance of 7 parts per million for residues of DDT in or on the fat of meat from

cattle, goats, sheep, horses, and hogs (§ 120.147). Animals that consume DDT in feed may accumulate considerably more of the chemical in their fat than is present in the feed itself, and a long time may be required on a diet free of DDT to reduce excessive residues to the tolerance level. It has not been established under what conditions of feeding, if any, apple pomace containing less than 7 parts per million of DDT can be fed to animals without causing the meat from such animals to contain residues in excess of the tolerance. Therefore, unless a grower of meat animals is in a position to establish that the DDT residue in the apple pomace and the conditions of feeding are such that the meat from such animals will be within the established tolerance, apple pomace should not be used in the feeding of meat animals.

[27 F.R. 12092, Dec. 6, 1962, as amended at 32 F.R. 4059, Mar. 15, 1967]

§ 120.147c DDT and its related degradation products in milk.

Tolerances of 0.05 part per million are established for residues in milk for each or any combination of the following: DDT, DDD (1,1-dichloro-2,2-bis (*p*-chlorophenyl) ethane), and DDE (1,1-dichloro-2,2-bis (*p*-chlorophenyl) ethylene). These tolerances are not established to provide for residues from the purposeful use of DDT, DDD, or DDE on dairy cattle, in dairy barns, or on the crops intended to be used for feeding dairy cattle.

[32 F.R. 4060, Mar. 15, 1967]

* * *

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 23812

ENVIRONMENTAL DEFENSE FUND, INCORPORATED, IRENE LOPEZ, ELVIRA GARDUNO, KATHY RADKE, MARILYN VITTOR, LEIGH ROYCROFT AND JUAN ZAMORA,

Petitioners,

v.

UNITED STATES DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ROBERT H. FINCH, SECRETARY,

Respondents.

Petition For Review Of An Order Of
The Commissioner of Food and Drugs

BRIEF FOR RESPONDENTS

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TABLE OF CONTENTS

TABLE OF CITATIONS

Cases:

Cases--Continued

Cases - Continued — Page

Statutes

Statutes - Continued

Statutes - Continued — Page

Miscellaneous

NOTE: Joint appendix of the parties will be in effect (1) portions of the record and (2) the Mrak Commission Report in its entirety. For convenience we have referred to the Mrak Report as Appendix B.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Whether the Delaney Clause of the Food Additive Amendments to the Federal Food, Drug, and Cosmetic Act, adopted in 1958, applies to the Pesticide Chemical provisions of the Act, which were enacted four years earlier in 1954.

2. Whether it was feasible for the Commissioner of Food and Drugs to establish a zero tolerance for the persistent pesticide DDT before the Secretary of Agriculture has cancelled the DDT registrations, thereby reducing DDT residues in the environment.

3. Whether petitioners submitted reasonable grounds in support of their petition that proposed an immediate zero tolerance for the persistent pesticide DDT.

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STATEMENT OF THE CASE

Jurisdiction

This is a statutory proceeding for judicial review of an Order of the Commissioner of Food and Drugs[1] refusing to approve a pesticide petition filed by petitioners pursuant to Section 408(m) of the Federal

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1/ Hereinafter referred to as "the Commissioner".

Food, Drug, and Cosmetic Act,[2] 21 U.S.C. 346a(m). On December 29, 1969, a petition for review of this Order was filed with this Court. Jurisdiction to review the administrative action exists by virtue of Section 408(i) of the Act, 21 U.S.C. 346a(i).

The Statutory Scheme

There are two federal statutes that regulate the use of pesticides: the Federal Insecticide, Fungicide, and Rodenticide Act,[3] 7 U.S.C. 135-135k, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301-392.

Under the FIFRA, every economic poison[4] that is marketed in interstate commerce is required to be registered with the Secretary of Agriculture. 7 U.S.C. 135b(a). Before a registration is issued, an applicant must submit certain information to the Secretary. 7 U.S.C. 135b(a)(1)-(4), and (b). If the composition of the economic poison is such as to warrant the proposed labeling claims for it, and if the required information has been filed, the Secretary will issue a registration for the article. 7 U.S.C. 135b(b). If a registration is refused, suspended, or cancelled, the FIFRA specifies certain procedural safeguards

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2/ 21 U.S.C. 301 et seq.; hereinafter referred to as "the Act".

3/ Hereinafter referred to as "FIFRA".

4/ The term "economic poison" is defined by 7 U.S.C. 135(a). DDT, the subject of these proceedings, is an economic poison.

which enable the applicant for registration or the registrant to request that the matter be referred to an advisory committee and to request a public hearing. 7 U.S.C. 135b(c). Final orders of the Secretary that are issued after referral to the committee or after a public hearing has been held are subject to appellate review. 7 U.S.C. 135b(d).[5]

Failure to register an economic poison that has, among other things, been shipped, or delivered for shipment, in interstate commerce subjects the violator to criminal prosecution. 7 U.S.C.135a(a)(1). The economic poison can also be seized if it has been transported in interstate commerce without a registration in effect. 7 U.S.C. 135g(a)(1)(B).

The Federal Food, Drug, and Cosmetic Act, on the other hand, places limitations on pesticide chemical residues in or on raw agricultural commodities.[6] 21 U.S.C. 346a, the Pesticide Chemicals Amendment [Public Law 83-518, 83rd Cong., 2d Sess., 68 Stat. 511 (1954)], was added to the Act in 1954. It provides that certain pesticide chemicals are unsafe for use in or on raw agricultural commodities unless (1) a tolerance has been established for this use and the pesticide chemical in or on the raw agricultural commodity does not exceed the tolerance, or unless (2) it has been exempted from the necessity of a tolerance. 21 U.S.C. 346a(a). Any raw agricultural commodity that contains a pesticide

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5/ Approximately 900 economic poisons are presently registered for use against 2,000 pest species [App. B 189].

6/ The term "pesticide chemical" is defined by 21 U.S.C. 321(q). DDT is a pesticide chemical. The term "raw agricultural commodity" is defined by 21 U.S.C. 321(r).

chemical in excess of the established tolerance or which contains a pesticide chemical which has not been formally exempted is deemed to be adulterated, within the meaning of 21 U.S.C. 342(a)(2)(B). Adulterated raw agricultural commodities that are shipped in interstate commerce or held for sale after shipment in interstate commerce are subject to seizure. 21 U.S.C. 334(a)(1). Other means of enforcement within the Act are criminal prosecution [21 U.S.C. 331] and injunction proceedings [21 U.S.C. 332(a)]. See generally United States v. Bodine Produce Co., Inc., 206 F. Supp. 201 (D. Ariz., 1962).[7]

The Act gives the Secretary of Health, Education, and Welfare the authority to promulgate regulations establishing tolerances or exemptions [21 U.S.C. 346a(b)-(c)], and provides detailed procedures that he must follow [21 U.S.C. 346a(d)-(e)]. In establishing tolerances, the Secretary is required to give appropriate consideration, among other relevant factors, "to the necessity for the production of an adequate, wholesome, and economical food supply" [Emphasis added]. 21 U.S.C. 346a(b). Exemptions can be established only when a tolerance is not necessary to protect the public health. 21 U.S.C. 346a(c).[8]

7/ Recognizing that some pesticide residues cannot be removed when a raw agricultural commodity has been subjected to processing, the Act also provides that processed foods shall be deemed adulterated if they contain any residue in excess of the tolerance prescribed for the raw agricultural commodity. 21 U.S.C. 342(a)(2)(C).

8/ Exemptions from the requirement of a tolerance are set forth in 21 C.F.R. 120.1001 et seq.

Any person who has registered, or who has submitted an application for the registration of, an economic poison under the FIFRA may file a pesticide petition with the Secretary proposing the issuance of a regulation establishing a tolerance or an exemption. 21 U.S.C. 346a(d)(1). The petition must contain data showing (1) the name, chemical identity, and composition of the pesticide chemical; (2) the amount, frequency, and time of application of the chemical; (3) full reports of investigations made with respect to the safety of the chemical; (4) the results of tests on the amount of residue remaining, including a description of the analytical methods used; (5) practicable methods of removing residue which exceeds any proposed tolerance; (6) proposed tolerances for the chemical if tolerances are proposed; (7) reasonable grounds in support of the petition. 21 U.S.C. 346a(d)(1). After considering this data, the opinion of the Secretary of Agriculture as to whether the pesticide chemical is useful for the purpose for which a tolerance is sought [21 U.S.C. 346a(b) and (1)], and, if requested by the person filing the petition or by the Secretary, the report and recommendations of an advisory committee selected by the National Academy of Sciences [21 U.S.C. 346a(d)(3) and (g)], the Secretary either publishes a regulation establishing a tolerance or an exemption. 21 U.S.C. 346a(d)(2)-(3). The tolerance may be established at zero level if the scientific data does not justify a greater tolerance.

The Act also permits the Secretary, upon his own initiative or upon the request of any interested person, to propose the issuance of a tolerance regulation or an exemption regulation. 21 U.S.C. 346a(e).

If an interested person submits such a pesticide petition, the identical information required of pesticide registrants by 21 U.S.C. 346a(d)(1) must be submitted, and the administrative review procedures are essentially the same as hereintofore described. 21 C.F.R. 120.29.

The Act also provides that any person adversely affected by the final regulation that is promulgated may file objections and request a public hearing. 21 U.S.C. 346a(d)(5). After completion of the hearing, the Secretary is authorized to issue a final order based on substantial evidence of record. Id. Judicial review can then be sought in the Court of Appeals by any person adversely affected by the Secretary's final order. 21 U.S.C. 346a(i).

Finally, the Act authorizes the Secretary to prescribe by regulation the procedure by which tolerance and exemption regulations that have already been established may be amended or repealed. 21 U.S.C. 346a(m) This procedure[9] must conform to the procedure provided for the promulgation of tolerance regulations. Id.

As is readily apparent from this brief examination of the two statutes, they supplement one another and are interrelated in their practical operation. An interagency agreement exists between the two Departments and with the Department of the Interior that provides for coordination

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9/ 21 C.F.R. 120.32

in reviewing pesticide applications. 29 Fed. Reg. 5808 (1964).[10] The Department of Agriculture generally will not register a pesticide unless the Department of Health, Education, and Welfare establishes a tolerance or an exemption. Conversely, a tolerance is not normally granted until a registration application has been filed. Most manufacturers file a registration application and a tolerance or exemption petition at the same time so that the agencies can process them simultaneously.

History Of These Proceedings

On October 7, 1969, petitioners filed a pesticide petition with the Food and Drug Administration, pursuant to 21 U.S.C. 346a(m) and 21 C.F.R. 120.32, proposing the issuance of a regulation to repeal all tolerances for the pesticide chemical DDT on raw agricultural commodities[11] [App. A pg. 1]. Since the basis for the pesticide petition was "new data" as to the toxicity of DDT, petitioners attempted to comply with the last sentence of 21 C.F.R. 120.32(b) by submitting their data in the form specified by 21 C.F.R. 120.7(b) ["Procedure for filing petitions ... proposing tolerances or exemptions for pesticide residues in or on raw agricultural commodities."] As indicated supra, this form is identical to that which Congress required pursuant to 21 U.S.C. 346a(d)(1).

10/ On January 28, 1970, a new "Interdepartmental Agreement For Protection Of The Public Health And The Quality Of The Environment In Relation To Pesticides" was signed by the three Departments. The agreement, effective upon signature, has not yet been published in the Federal Register.

11/ Tolerances for DDT are set forth in 21 C.F.R. 120.147. The insecticidal properties of DDT, a mixture of 1,1,1-trichloro-2,2-bis (p-chlorophenyl) ethane and 1,1,1-trichloro-2-(o-chlorophenyl)-2-(p-chlorophenyl) ethane, were discovered in Switzerland in 1939. At first it was used mostly by the military for control of diseases such as malaria and typhus, but by 1945 it became commercially available to the public (App. B 44-6, 296].

The petition that was submitted to the Food and Drug Administration included items (A)-(D) specified by 21 U.S.C. 346a(d)(1), but no data was included concerning practicable methods for removing DDT residues from the environment if the regulation proposed by petitioners were adopted [item (E)]. On the contrary, petitioners conceded that DDT, a persistent pesticide, would remain in the environment "over a long period of time" [App. A 63].

In support of the petition, petitioners alleged that a recent study indicated that DDT caused tumors in animals and that, therefore, the Secretary had no discretion whatever, and was compelled by the Delaney Clause [21 U.S.C. 348(c)(3)(A)] of the Food Additives Amendment [21 U.S.C. 348] and by the Color Additives Amendment [21 U.S.C. 376] to repeal the tolerances for DDT on raw agricultural commodities, which, of course, were not adopted under either of the cited Amendments.

On October 31, 1969, petitioners filed a supplemental petition requesting that the tolerances for DDT on raw agricultural commodities be immediately repealed and set at zero [App. A 90]. The petitioners were once again unable to set forth any practicable methods of removing DDT residues from the environment. To the contrary, they recognized "that because of the great mobility, persistence, and solubility characteristics of DDT, it is not possible to achieve a zero tolerance by administrative fiat." [App. A 95]. Despite this acknowledgement, petitioners still urged the Secretary to establish a zero tolerance for DDT in raw agricultural commodities.

At the very time the Food and Drug Administration had the pesticide petition for consideration, the Secretary's Commission on Pesticides and Their Relationship to Environmental Health was completing its extensive report to Secretary Finch. This report considers the problems of pesticides in the environment on a much broader base than the one presented in the petition. Pending the issuance of this final report prepared by the expert advisory group, the Commissioner did not act on the petition to repeal the DDT tolerances or to establish a zero tolerance for DDT in raw agricultural commodities [App. A 104].

On November 11, 1969, the Commission forwarded fourteen recommendations to the Secretary.[12] One proposed the elimination within two years of all uses of DDT in the United States except those uses essential to the preservation of human health or welfare which were approved unanimously by the Secretaries of Health, Education, and Welfare, Agriculture, and Interior [App. B 8]. The Commission, recognizing that unavoidable residues of DDT from past uses will continue to be present in the soil, water, air, and food for a period of years, also concluded that it is not practical to attempt to eliminate DDT residues from food by the establishment of zero tolerances [App. B 9-14].

12/ Report of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health [App. B]. The complete Report, also known as the Mrak Report because the Commission's chairman was Dr. Emil M. Mrak, Chancellor Emeritus of the University of California at Davis, was forwarded to Secretary Finch on December 5, 1969.

On the basis of the recommendations in the Mrak Report, the Commissioner, on December 8, 1969, notified petitioners that their pesticide petition was not acceptable for filing [App. A 101]. The refusal to publish their proposed regulation in the Federal Register was based on the absence of a showing that the establishment of a zero tolerance for DDT in raw agricultural commodities was practical and that, therefore, reasonable grounds to support the tolerance had not been presented.

This appeal followed.[13]

ARGUMENT

Introduction

Petitioners' case here is based upon a fundamental misconception that the Delaney Clause of the Food Additive Amendments, enacted in 1958,

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13/ Respondents seriously question whether each of the petitioners is an "interested person" as required by 21 C.F.R. 120.32(a), and whether each of them has a "substantial interest" in the DDT tolerances on raw agricultural commodities as required by 21 C.F.R. 120.32(b). Despite these reservations, the Agency proceeded to handle the pesticide petition in an expeditious and judicious manner. Respondents also seriously question whether petitioners have standing in this Court of Appeals to seek judicial review of a letter from the Commissioner which refused to publish their proposed regulation in the Federal Register. We are aware that this is the position being taken by the Department of Agriculture in Environmental Defense Fund v. Hardin, (C.A. D.C., No. 23813), that this Court has deferred decision on the Government's motion to dismiss and ordered that briefs on the merits be submitted, and that the Government has filed a motion for reconsideration. The filing of this brief by the Department of Health, Education, and Welfare does not imply that we believe the position taken by Secretary Hardin is not well-founded. On the contrary, the procedural differences between the two applicable statutes, the impracticality of a zero tolerance for DDT, and the impossibility of achieving the purposes the petitioners have requested has compelled us to seek affirmance of the Commissioner's "order" in this Court.

became applicable to the Pesticide Chemicals Amendments, enacted four years earlier, and stripped the Secretary of all discretion but to establish a zero tolerance for DDT residues on raw agricultural commodities upon a showing that DDT had induced cancer in test mice.

Clearly, the Delaney Clause was not a part of the pesticide control provisions. And just as clearly, the Secretary of Health, Education, and Welfare could not grant and enforce the zero tolerances requested by the petition so long as DDT is registered for agricultural and other uses.

Instead of undertaking a course of action that would be impracticable, the Secretary, the Secretary of Agriculture, and the Environmental Quality Council initiated steps to reduce the use of DDT and other persistent pesticides in response to an expert commission's recommendations.

We submit that the action taken was responsible action. The publication and scheduling administrative actions on the basis of the petition filed was not warranted because the relief sought--the total elimination of DDT from the environment--could not be granted in any such proceeding. Instead, coordinated actions with the Secretary of Agriculture were indicated, the appropriate actions were initiated, and in the light of that there were no reasonable grounds for publication and processing of the petition.

I.

The Delaney Clause Does Not Apply To Tolerances For Pesticide Chemicals In Or On Raw Agricultural Commodities.

Petitioners, realizing that the pesticide provisions of the Act clearly support the Commissioner's order, attempt to evade that section and instead invoke the Delaney Clause of the food additive provisions. They argue that the clause requires the Secretary immediately to establish zero tolerances for DDT in or on raw agricultural commodities, because new data has appeared concerning tumors in mice fed very large doses of DDT. This argument is contrary to the clear provisions of the Act itself.

The Delaney Clause, 21 U.S.C. 348(c)(3)(A), was added to the Federal Food, Drug, and Cosmetic Act as part of the Food Additives Amendment of 1958 [Public Law 85-929, 85th Cong., 2d Sess., 72 Stat. 1784 (1958)]. The clause provides that "no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal" [Emphasis added]. There is no such provision in the pesticide provisions of the Act, which were adopted four years earlier. 21 U.S.C. 346a.

The language of the Delaney Clause explicitly states that it applies only to food additives, and not to pesticide chemicals. The term "food additive" is defined by 21 U.S.C. 321(s), and that definition specifically excludes DDT on raw agricultural commodities:

> The term "food additive" means ... except that such term does not include--
>
> (1) a pesticide chemical in or on a raw agricultural commodity; or
>
> (2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity....
> [Emphasis added].

It is obvious that petitioners have intentionally ignored or negligently overlooked this express Congressional mandate which excludes pesticide chemicals such as DDT from being classified as food additives and thus being subject to 21 U.S.C. 348. Accord United States v. Bodine Produce Co., Inc., 206 F. Supp. 201 (D. Ariz., 1962) where the Court, in discussing the 1958 Food Additives Amendment, stated at p. 210:

> There, Congress tackled the problems of food additives in processed foods in depth. It drew a sharp line between the Food Additives Amendment and the Pesticide Chemicals Amendment. Thus in the definition of "food additive" it excluded pesticide chemicals in or on raw agricultural commodities [citing 21 U.S.C. 321(s)]. The Congressional intent to leave the Pesticide Chemicals Amendment undisturbed is confirmed by the legislative history which also explains the purpose of the exemption proviso [Citing S. Rep. No. 2422, 1958 U.S. Code Cong. & Adm. News, p. 5304]. [Emphasis added]

We see no justification for petitioners to distort the clear meaning of the statute. See also the concurring opinion of Justice Rutledge in United States v. Sullivan, 332 U.S. 689, 699 (1948):

> The Act is long and complicated. Its numerous provisions treat the very different subjects of drugs, food and cosmetics alike in some respects, differently in others. The differences are as important as the similarities, and cannot be ignored. [Emphasis added].

The Delaney Clause can only be invoked if a food additive petition is filed with the Agency pursuant to 21 U.S.C. 348(b). We respectfully direct the Court's attention to 21 U.S.C. 348(c). As is readily apparent, the Delaney Clause is included under the subsection titled "Action on the Petition". Until a food additive petition is submitted, the Delaney Clause does not become operative. Once a food additive petition is filed, this provision gives the Secretary authority to deny the petition when scientific evidence establishes that the food additive induces cancer in man or animal. Rossi v. Finch, ___ F. Supp. ___ (N.D. Cal., Feb. 2, 1970) [Copy attached].

In Rossi v. Finch, supra, a three judge Federal Court recently considered the circumstances under which the Delaney Clause becomes applicable. There, plaintiffs sought an injunction restraining the Commissioner from enforcing his order removing the chemical compound cyclamate from the list of substances that are generally recognized as safe for unrestricted use in food.[14] As a consequence of his order, food containing cyclamate became adulterated within the meaning of 21 U.S.C. 342(a)(2)(C). Plaintiffs alleged that the Commissioner's order was based on the Delaney Clause and that the clause was unconstitutional. We quote the pertinent section of the Court's decision upholding the Commissioner's action:

14/ 21 C.F.R. 121.101

> Plaintiffs contend that the Commissioner's order deleting all cyclamates from the list of substances that are generally recognized as safe for their intended use and restricting the use and sale of foods containing cyclamates were made under authority found in the Delaney Amendment .... However, the Delaney Amendment is operative only upon petitions which are filed to determine the safety of new food additives or those that were not exempted at the time the Delaney Amendment was enacted in 1958. See 21 U.S.C. §§321(s), 348. The cyclamates are among those food additives which were exempted by inclusion in the list of additives generally recognized as safe at the time Section 409 was added to the Federal Food, Drug, and Cosmetic Act. 24 Fed. Reg. 9368 (1959). The recent orders of the Commissioner removed cyclamates from the list and imposed restrictions on its use. See 34 Fed. Reg. 17063 (1969). Such action by the Commissioner, under properly delegated authority by the Secretary, is authorized under 21 U.S.C. §371, without any reliance on the provisions of 21 U.S.C. §348. [Emphasis added]

As in Rossi, petitioners' reliance upon the Delaney Clause is clearly without merit.

Petitioners' reliance on Bell v. Goddard, 366 F.2d 177 (C.A. 7, 1966), is misplaced. That case does not involve either the pesticides or the food additive provisions of the Act. Instead, it involved the withdrawal of a new drug application pursuant to 21 U.S.C. 355(e). In affirming the Commissioner's order, the Court had occasion to consider the Delaney Clause, and it stated what is self-evident from reading the clause: that a food additive petition will not be approved if the additive induces cancer in any strain of test animal under any circumstances [366 F.2d at 181]. In other

words, the Court merely added the word "any" to the language Congress enacted in 1958. Instead of supporting petitioners' argument, Bell v. Goddard, supra, is clearly contrary.

Petitioners base much of their case upon statements made by Arthur S. Flemming, former Secretary of the Department (Br. 13-16, 19-25). While petitioners say this was a contemporaneous construction of the Pesticide Chemicals Amendment or the Food Additive Amendment, it was neither. It was instead testimony presented in 1960 in support of the Color Additives Amendments adopted that year. Insofar as it related to the Pesticide Chemicals Amendment, Secretary Flemming was announcing a policy, and not a contemporaneous construction for provisions enacted 6 years earlier.

Moreover, contemporaneous administrative construction is not applicable here because (1) the Delaney Clause is not ambiguous and because (2) Secretary Flemming was only announcing a departmental policy.

The phrase from Norwegian Nitrogen Products Co. v. United States, 288 U.S. 294 (1933), appearing at page 18 of Petitioners' Brief, and which they allege supports their argument, is quoted out of context. For the benefit of the Court, we set out the entire quotation:

> True indeed it is that administrative practice does not avail to overcome a statute so plain in its commands as to leave nothing for construction. True it also is that administrative practice, consistent and generally unchallenged, will not be overturned except for very cogent reasons if the scope of the command is indefinite and doubtful [citing cases]. The practice has peculiar weight when it involves a contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion, of making the parts work efficiently and smoothly while they are yet untried and new. [288 U.S. at 315].

The correct legal principle to be derived from Norwegian Nitrogen is that contemporaneous administrative construction cannot change the clear language of the statute. Accord Land O'Lakes Creameries, Inc. v. Commodity Credit Corp., 265 F.2d 163 (C.A. 8, 1959); Potomac Electric Power Co. v. Hazen, 90 F.2d 406 (C.A. D.C., 1937), cert. den. 302 U.S. 692.

If this Court should adopt petitioners' argument, it would have to ignore the plain terms of the statute. Six Federal judges, four from the Court of Appeals and two from the District Court, have previously construed the Delaney Clause, and in so doing they had no problem determining its clear meaning and applicability. The cases of Rossi v. Finch, supra, and Bell v. Goddard, supra, hold that the clause is susceptible of only one interpretation: it prohibits the Agency from approving food additive petitions under

certain carefully delineated circumstances. Since the language of the enactment is not ambiguous, it follows that petitioners' argument is wholly devoid of merit.

Petitioners repeatedly, and we believe intentionally, confuse the procedures for establishing an initial tolerance for a pesticide chemical [21 U.S.C. 346a(b), (d), and (e)], with the procedures for amending a tolerance that has already been promulgated [21 U.S.C. 346a(m)]. Secretary Flemming's statements concerning the cranberry incident and his testimony before Congress refer to a proposed tolerance for a new pesticide. This proceeding is concerned with a pesticide chemical long in use and ubiquitous in the environment because of its persistence. We respectfully request this Court to re-read each of the Secretary's statements which appear on pages 19-25 of Petitioners' Brief. Not one of them refers to the present situation where a pesticide tolerance regulation is already in effect.

When Secretary Flemming recommended the initiation of seizure proceedings against aminotriazole contaminated cranberries in 1959, he did so because no tolerance regulation was in effect for the pesticide chemical. Accordingly, all raw agricultural commodities containing residues of this chemical were adulterated within the meaning of 21 U.S.C. 342(a)(2)(B). At that time, the Secretary announced a policy decision that his administration would not establish a tolerance for aminotriazole or any other pesticide chemical when there was scientific evidence that the chemical had caused cancer in test animals. He did

not address himself to the policy issues that are involved in the orderly phasing out of an existing pesticide for which tolerances have been established. Since there is no statutory provision comparable to the Delaney Clause in the pesticide provisions of the Act which would require the Secretary to establish a zero tolerance for DDT, he had the discretion to establish his own safety policy. Policy adopted for a different situation by a prior Secretary obviously is not legally binding on his successors. American Trucking Ass'ns, Inc. v. Atchison Topeka & Santa Fe Ry., 387 U.S. 397, 416 (1967); National Broadcasting Co. v. United States, 319 U.S. 190, 225 (1942); Maxwell Co. v. NLRB, 414 F.2d 477, 479 (C.A. 6, 1969).[15]

In referring to pesticide petitions to establish an initial tolerance regulation, 21 U.S.C. 346a(b) provides that "... the Secretary may establish the tolerance ... at zero level if the scientific data ...

15/ It is interesting to note that the word "policy" appears eleven times in the quotations cited by petitioners at pages 19-25 of their brief. Note also that Secretary Flemming, unlike petitioners, was able to recognize the obvious differences between the 1954 pesticide amendments and the 1958 food additive amendments. Referring to the Delaney Clause, he said: "... the earlier Pesticide Amendment, which is applicable to the cranberries, does not contain such a specific provision...." HEW News Release, Nov. 9, 1959, quoted at page 19 of Petitioners' Brief; and "... the Pesticide Chemicals Amendment ... does not contain the proviso." H.R. Rep. No. 1761, 86th Cong., 2d Sess. (1960), quoted at page 23 of their brief.

does not justify the establishment of a greater tolerance." [Emphasis added]. Referring to the same initial tolerances, 21 C.F.R. 120.5 provides, in part: "A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because ... [t]he chemical is carcinogenic to ... one or more of the species of the test animals used, when fed in the diet of such animals." [Emphasis added].

It is obvious that Congress delegated to the Secretary the authority to decide acceptable residue levels, and that the exercise of that duty involves a measure of judgment to protect the public health. Contrary to petitioners' argument that Congress intended the Delaney Clause to apply to the Act in general, the clause itself is expressly limited and there is no statutory authority requiring the Secretary to disapprove pesticide petitions or to establish a zero tolerance upon a showing of cancer in test animals.

In administering the Pesticide Chemicals Amendment, the Secretary has discretion, not permitted by the Delaney Clause for action on food additive petitions, to consider such factors as the dosage that caused animal tumors, the extrapolation of this data to the practical problem of safety to man, to the need for producing an adequate and wholesome food supply, and the practical steps that may be required to phase a long used, persistent pesticide out of man's foods. On the basis of relevant factors such as these, and full consideration of the extensive report of the expert commission on

pesticides, the Secretary and the Commissioner concluded that it was neither necessary nor practicable to establish zero tolerances for DDT in all raw agricultural commodities. The phase out planned was a rational and acceptable course of action.[16]

II

The Commissioner Was Not Required To Act On The Pesticide Petition Until The Department of Agriculture Procedures Were Satisfied.

We have previously discussed the interrelationship between the two applicable Federal statutes and the close working relationship that is required between the Departments charged with enforcing them. A pesticide registration will not be granted by the Department of Agriculture unless a tolerance is established by the Department of Health, Education, and Welfare at the same time. The repeal of a tolerance for

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16/ We decline to burden this brief, and thereby dignify petitioners' argument, by replying to their suggestion that the color additive provisions of the Act, 21 U.S.C. 376, apply to pesticides. The term "color additive" is defined by 21 U.S.C. 321(t)(1), but subsection (3) excepts pesticide chemicals. Note also that color additives are expressly excluded from the definition of the term "food additive" by 21 U.S.C. 321(s)(3). The enactment of these amendments in 1960 with a cancer provision somewhat comparable to the Delaney Clause of the Food Additives Amendment demonstrates that the Congress has made that principle applicable in some instances and not in others. If, as petitioners argue, the Delaney clause applies to all additives to food there would have been no reason to enact it again in the Color Additives Amendment two years later.

a persistent pesticide such as DDT also requires inter-departmental coordination, but it is not possible for the two Departments to act simultaneously. As long as DDT is registered for use, it can be used as a pesticide and will be present in the environment. The cancellation of the registrations is a necessary first step to the elimination of DDT from the environment. The establishment and enforcement of zero tolerances for DDT follow that action. The Secretary of Agriculture is the only person who can cancel the registrations, and the FIFRA is the only legislation under which such registrations can be withdrawn.

The reason for this procedure is self-evident. DDT belongs to a class of compounds known as chlorinated hydrocarbons. The outstanding feature of this group is their prolonged residual effect (i.e., persistence) [App. B 63, 245]. The Mrak Report defines "persistence times" as those periods required for a 5 to 100 percent loss of the pesticides' activity under normal environmental conditions and rates of application [App. B 104]. Accordingly, it calculates the persistence time for DDT as two to five years [App. B 104].[17]

17/ A comprehensive study recently completed by the Department of Agriculture showed that under experimental conditions thirty-nine percent of the original application of DDT remained in the soil after seventeen years. The time for half of the original amount of DDT to disappear was ten and one-half years. Nash and Woolson, Persistence of Chlorinated Hydrocarbon Insecticides in Soils, 157 Science 924 (1967).

As a result of its persistence, DDT remains in the air, water and soil for a sufficient length of time to be carried over from season to season and from one crop to the next [App. B 260]. As time elapses, the chemical gradually disappears until all residues from the original application have been eliminated. This phenomenon means that in order to effectively establish and enforce a zero DDT tolerance in or on raw agricultural commodities, the Secretary of Agriculture must first cancel all DDT registrations pursuant to 7 U.S.C. 135b(c). Once the statutory procedures promulgated by Congress have been satisfied and the DDT registrations are cancelled, the pesticide could no longer be distributed in interstate commerce without being in violation of the law. Thereupon, the use of DDT would be sharply curtailed, or altogether eliminated, and residues in the environment from prior use would begin to disappear. Only then would there be a reasonable basis for the promulgation and enforcement of a zero tolerance for DDT in raw agricultural commodities. Thereafter, the Commissioner could grant

the relief petitioners presently request and propose a regulation which would establish a DDT tolerance of zero. To require the Commissioner to take such action before the DDT registrations are cancelled is contrary to the statutory scheme, unreasonable, impractical, and could result in a chaotic situation by classifying a great many of our foods as adulterated.

Thus, we contend that until the Department of Agriculture has completed the needed steps to cancel or withdraw DDT registrations, the establishment of zero tolerances for the chemical in or on raw agricultural commodities could have no practical significance in removing the pesticide from man's environment. And that is the relief the petitioners seek in the petitions filed with the two Departments and by the two actions for judicial review that are before this Court. The Secretary of Agriculture has pointed out in his motion to dismiss that the administrative process has not been exhausted, and that cancellation of registrations cannot be effected otherwise.

III.

Petitioners Did Not Submit Reasonable Grounds In Support of Their Pesticide Petition.

Very little of Petitioners' forty-five page Brief addresses itself to the particular issue that confronts this Court: whether the Commissioner of Food and Drugs acted properly when he refused to publish the proposed regulation on the ground that no evidence had been submitted to establish that zero tolerances for DDT in raw agricultural commodities would be practical. Instead of addressing themselves to this issue, the only reason specified by the Commissioner's letter of December 8, 1969, petitioners present an emotional argument concerning the effects of DDT on birds, fish, and other animals.[18] These, of course, may be matters for consideration by the Secretary of Agriculture in cancelling registrations, but they have little or no relevance to the establishment of a zero DDT tolerance for raw agricultural commodities.

Regulation 21 C.F.R. 120.32, which implements the applicable statutory provision, 21 U.S.C. 346a(m), and which is patterned after the provisions for the establishment of initial tolerances or exemptions [21 U.S.C. 346a(d)(1)], provides that every petition proposing the amendment or repeal of a pesticide tolerance must be

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18/ The Mrak Report had this to say about such emotional arguments:

> Reporting and exaggerating the danger of pesticide usage without equal treatment of the beneficial aspects of pesticides threatens to retard the advancing technology required to meet food and public health demands around the world [App. B 80].

accompanied by, among other things, practicable methods for removing any pesticide residue that exceeds the proposed tolerance. See 21 C.F.R. 120.7(b). Unless this data is included in such a petition, the Congressional and administrative requirements have not been satisfied and relief cannot be granted. See S. Rep. No. 1635, 83rd. Cong., 2d Sess. 8 (1954) and H.R. Rep. No. 1385, 83rd Cong., 2d Sess. 8 (1954), where Congress stated:

> The data to be contained in a petition include information about ... practicable methods for removing the residue which exceeds any proposed tolerance ... and reasonable grounds to support the petition.... What is contemplated is data adequate to permit an accurate appraisal of safety to protect the public health. In this respect the data as to a particular chemical will depend upon many available factors, including its ... rate of disappearance. The emphasis to be placed on any such factor will similarly depend on the particular pesticide chemical under consideration and its proposed usage. In some cases it is to be expected that, despite extensive research, ... methods of residual removal may not be available.... It is understood that data as to practicable methods for removing residue are required only in cases where the residue would otherwise exceed the proposed tolerance. [Emphasis added].

Here, it is uncontroverted that petitioners have failed to provide the Agency with any data setting forth practicable methods of removing DDT residues. It is also uncontroverted that such data will not be forthcoming because DDT residues will remain in the environment as long as DDT registrations remain in effect permitting the pesticide to be used. Since the statutory burden of presenting reasonable grounds in support of a tolerance is upon petitioners, and since no data was submitted to the Food and Drug Administration to establish how the DDT

in excess of zero tolerances could be removed from raw agricultural commodities, it necessarily follows that reasonable grounds in support of the petition were not presented. Cf. Turkel v. Food & Drug Administration, 334 F.2d 844 (C.A. 6, 1964). Clearly, the Commissioner was not arbitrary or capricious when he refused to publish petitioners' proposed regulation. The relief requested was beyond the Secretary's power so long as the registrations remained in effect and DDT remained in the air, soil, and water. Cf. Dyestuffs & Chemicals, Inc. v. Flemming, 271 F.2d 281 (C.A. 8, 1959).

If the Commissioner of Food and Drugs were required to publish every pesticide petition that is submitted, this Department and the Federal courts would be overburdened with administrative proceedings and suits seeking impractical tolerances. That is why Congress has required that each petition must be accompanied by evidence showing that the tolerance is reasonable and attainable.

Petitioners allege that the Commissioner's refusal to publish this proposal precludes the marshalling of information for the benefit of the administrative agency [Brief for Petitioners, p. 40]. We agree that in the normal course of events publication would give interested members of the public the opportunity comment and perhaps provide the Agency with new ideas or proposals.

Here, however, the Secretary several months before petitioners submitted their zero tolerance proposals had established a broadly based expert Commission on Pesticides and Their Relationship to Environmental Health [App. B]. The Commission, composed of

representatives from the scientific community, academics, private industry, and the Federal and State governments [App. B vi-xvii], was appointed in April 1969, and "charged with the responsibility of gathering all available evidence on both the benefits and risks of using pesticides, evaluating it thoroughly, and reporting their findings and recommendations to Secretary Finch." [App. B 5].

After meticulously reviewing over 5,000 references to scientific research,[19] the Commission unanimously approved fourteen recommendations [App. B 5]. These recommendations can generally be classified into five categories: (1) initiate closer and improved cooperation among and within the agencies that regulate pesticides and between government and industry; (2) create permanent advisory groups to gather and evaluate pesticide information; (3) review the adequacy of current pesticide laws; (4) increase pesticide research; and (5) restrict the usage of persistent or hazardous pesticides [App. B 7-19]. This proceeding is concerned with the last recommendation.

Regarding DDT, the Mrak Commission recommended that all uses in the United States, except those essential to preserve human health and welfare and unanimously approved by the Departments of Health, Education, and Welfare, Agriculture, and Interior, be eliminated within two years [App. B 8]. In order to implement this

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19/ This contrasts sharply with the meager information in the petition.

recommendation, it is, of course, necessary that most DDT registrations be cancelled by the Secretary of Agriculture. DDT registrations for use to prevent or control human disease or necessary to produce an adequate food supply would not have to be cancelled under this approach.

In proposing the recommendation that most DDT uses be eliminated within two years, the Commission was faced with the complex and extremely difficult matter of tolerances and residues of the persistent pesticide in or on raw agricultural commodities. Unlike petitioners, it recognized that the environment was not susceptible of an over-night transformation and that a gradual reduction of tolerances would be essential to protect the Nation's food supply. In discussing residues and zero tolerances the Commission stated:

> Unavoidable residues ... will continue to occur in the soil, water, air, and food supplies for a period of years despite restrictions of usage in the United States. Reasonable methods must be established for the use of as much of the food supply as possible without hazard to human health [App. B 9].
>
> * * *
>
> It is, however, impractical to attempt to eliminate the residues of such pesticides from foods by the application of zero tolerance limits. Modern techniques have greatly increased the sensitivity of the analytical methods available when the zero tolerance concept was advanced. This fact must be recognized in judging the possibilities of hazards and establishing tolerance limits with a sufficient margin of safety to protect human health and welfare [App. B 10].
>
> * * *
>
> The imposition of restrictions on exposure, particularly from pesticide residues in food and water, should be accompanied by periodic review and adjustment of pesticide residue tolerances. Indiscriminate imposition of zero tolerance may well have disastrous consequences upon the supply of essential food and threaten the welfare of the entire Nation. Stepwise lowering of pesticide tolerance may in some cases be an effective and flexible instrument with which to execute policy. [App. B 11]. [Emphasis added].

Upon receipt of the Commissioner's report and recommendations, the Secretary announced, with the concurrence of the Secretary of Agriculture, that a program to phase DDT out of all but essential uses would be implemented. This, in the judgment of the Secretary, was the only practicable approach to the issues presented by the petition. It was a proper response to the petition.

The reason for the gradual phase-out approach recommended by the Commission is obvious. There is little dispute that DDT is present at detectable levels in almost all foods [App. B 138, 385]. The major source of DDT is those food classes representing products of animal origin (e.g. meat, fish, poultry, and dairy products) [App. B 136]. DDT in these foods results from indirect and environmental sources; not from direct application of the chemical to the animal [App. B 136, 385]. Despite any use restrictions now imposed on DDT, residues will be present for many years on these foods as well as on grains, fruits and vegetables. If a zero tolerance were imposed, almost all food in the United States would be adulterated within the meaning of 21 U.S.C. 342(a)(2)(B) or (C) because of pesticide residues in excess of the established tolerance. Removal of most foods from the market would present a frightening and deplorable situation, but one that is <u>not</u> a remote possibility, if the zero tolerance petitioners seek must be immediately imposed and enforced.

We commend petitioners on their ability to recognize that a major portion of our food supply would be threatened with confiscation if a zero tolerance were immediately established and enforced [Brief for Petitioners, p. 39]. It is remarkable that they were able to understand the seizure provisions of the Act, after such a gross misinterpretation of the pesticide and food additive provisions. However, they suggest that the Secretary can solve the residue problem by exempting from seizure all food that contains DDT residues which were applied prior to the effective date of the revised tolerances. Petitioners cite no statutory authority for this suggestion. The pesticide provision permitting the Secretary to exempt any chemical from the necessity of a tolerance [21 U.S.C. 346a(c)] has no applicability here. That provision refers to initial petitions where a quantitative restriction on the residue of such a chemical is not necessary to protect the public health, and not to the amendment or repeal of existing tolerances. S. Rep. No. 1635, supra at 7; H.R. Rep. No. 1385, supra at 8.

Unlike petitioners, we recognize that "simple answers are not forthcoming to most of the questions concerning human exposure to pesticides." [App. B. 246]. Also, unlike petitioners, the government will not "jump to hasty conclusions not warranted by the available data ...." [App. B 244]. That is why well-planned changes having a favorable effect on human health and welfare are essential. As succinctly stated by the Mrak Report: "In setting tolerances for pesticide residues in or on foods, the Department of Health, Education, and Welfare should be cognizant of the need for optimal human nutrition and food supply." [App. B 12].

Implementation of the Mrak Committee recommendations has already commenced. On November 25, 1969, the Department of Agriculture published notice in the Federal Register proposing to cancel all DDT registrations for the following: (1) all uses on shade trees; (2) all uses on tobacco; (3) all uses in or around the home except for control of disease; (4) all uses in aquatic environment, marshes, wetlands, and adjacent areas except those essential for the control of disease. 34 Fed. Reg. 18827 (1969). These registrations account for approximately thirty-five percent of the total DDT used in this country.[20] The same notice also announced that the Department was

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20/ Pursuant to 7 U.S.C. 135b(c), some registrants requested that the matter be referred to an advisory committee while others filed objections and requested a public hearing.

preparing to take identical action against all other non-essential uses of DDT and requested comments, within ninety days, from all interested persons.

As soon as DDT registrations are cancelled, this Department can make a concerted effort to review tolerance levels and reevaluate them in light of the available residue data reflecting the pesticide's decline in use. This procedure has recently been followed with success. In 1968, the Food and Drug Administration reexamined the tolerance levels for DDT in or on various raw agricultural commodities and concluded that some of the tolerances were higher than the amount reasonably required to cover the expected residues. Accordingly, new tolerances were proposed and adopted. 33 Fed. Reg. 2787 (1968). We respectfully submit that this procedure is the most reasonable approach that the Commissioner can take under the law. If a pesticide petition were submitted with reasonable evidence that the present DDT tolerances are too high and with a request for a reasonable tolerance reduction, the Commissioner could then publish such petition in the Federal Register.[21] But a zero tolerance is not now attainable.

21/ We do not mean to belittle the conservation efforts of petitioner Environmental Defense Fund, Inc. We recognize and applaud their continued efforts to protect man's environment.

The Commissioner is well aware that the purpose of the Act is to protect the public health. United States v. An Article of Drug ... Bacto-Unidisk, 394 U.S. 784 (1969); United States v. Wiesenfeld Warehouse Co., 376 U.S. 86 (1964); United States v. Dotterweich, 320 U.S. 277 (1943). However, in exercising his statutory responsibilities he is required to base his action "upon a conscientious judgment derived from a consideration of the facts and conditions in the situation to which the regulation is to be applied." Twin City Milk Producers Ass'n. v. McNutt, 122 F.2d 564, 566 (C.A. 8, 1941). That philosophy, together with the Commission's comprehensive report, guided him to reject petitioners' pesticide petition because a zero tolerance, instead of protecting the consumer, could do irreparable damage. See 21 U.S.C. 346a(b) which authorizes the Commissioner to give appropriate consideration to the necessity for the production of an adequate, wholesome, and economical food supply. We firmly believe that Congress did not require that such an unreasonable and unenforceable regulation as that proposed by petitioners be promulgated.

There is instead a practical solution to the DDT problem. It is the orderly elimination of the use of DDT by cancelling its registrations and then reducing the tolerances for DDT in or on raw agricultural commodities. This is the solution recommended by the Secretary's Commission on Pesticides, and it is the solution that is being pursued.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the Order of the Commissioner of Food and Drugs should be affirmed.

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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

LEO ERNEST ROSSI, ROBERT NIXTON, GOODIE WILLIS, LOUIS MOSCONI, JOANNE ROSSI, EARL STARNES, and PATRICIA CHILDRESS,

Plaintiffs,

v.

JOSEPH W. [illegible], Secretary of the Department of Health, Education and Welfare, and HERBERT L. LEE, JR., Commissioner of the Food and Drug Administration,

Defendants.

No. C-69-314-CJC

MEMORANDUM AND ORDER

This action is brought by the named plaintiffs purportedly on behalf of three classes of persons, to-wit: persons who are afflicted with obesity, persons who are afflicted by diabetes, and persons who generally desire to control food portions by utilizing artificial sweeteners known as cyclamates. The complaint is brought against the Secretary of Health, Education and Welfare and the Commissioner of the Federal Food and Drug Administration to enjoin the defendants from enforcing administrative orders allegedly [illegible] of the Federal Register, [illegible] § 348(c)(3)(i) thereof [illegible]).

SUPPLEMENT A

for relief is based on the contention that the Delaney Amendment is unconstitutional, thereby rendering administrative orders made pursuant thereto void.

The complaint is accompanied with a request that a three-judge court be convened under the provisions of 28 U.S.C. §§ 2282, 2284. The single judge who heard this request concluded that an injunction was being sought which would restrain the enforcement and operation of an Act of Congress and accordingly a three-judge court was convened to hear and determine the cause.

The defendants filed a motion to dismiss the action for failing to meet the jurisdictional requirements of a three-judge district court. This Court concludes that the motion should be granted.

Plaintiffs contend that the Commissioner's orders deleting all cyclamates from the list of substances that are generally recognized as safe for their intended use and restricting the use and sale of foods containing cyclamates were made under authority found in the Delaney Amendment. In this way plaintiffs claim standing to attack the constitutionality of the Delaney Amendment because they are aggrieved by the administrative orders in question. However, the Delaney Amendment is operative only upon petitions which are filed to determine the safety of new food additives or those that were not exempted at the time the Delaney Amendment was enacted in 1958. See 21 U.S.C. §§ 321(s), 348. The cyclamates are among those food additives which were exempted by inclusion in the list of additives generally recognized as safe at the time Section 409 was added to the Federal Food, Drug, and Cosmetic Act. 24 Fed. Reg. 9368 (1959). The recent orders of the Commissioner removed cyclamates fro

the list and imposed restrictions on its use. See 34 Fed. Reg. 17063 (1969). Such action by the Commissioner, under properly delegated authority by the Secretary, is authorized under 21 U.S.C. § 371, without any reliance on the provisions of 21 U.S.C. § 348. The validity of such orders is reviewable by the Courts of Appeals of the United States and not by the District Courts. 21 U.S.C. § 371(f).

Since plaintiffs' standing to contest the constitutionality of the Delaney Amendment depends upon the relationship of this Act of Congress to the administrative orders of the Commissioner restricting the use of cyclamates, and there being no such relationship, the action must be dismissed as one which fails to state a claim for relief within the jurisdiction of this Court.

Accordingly, it is hereby ORDERED that defendants' motion to dismiss be, and the same is hereby granted and the action is dismissed.

Dated: January _____ 1970.

O. D. HAMLIN
United States Circuit Judge

OLIVER J. CARTER
United States District Judge

WILLIAM T. SWEIGERT
United States District Judge

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of February 1970, I served two copies of the foregoing brief to counsel for the petitioners by mailing same, postage prepaid, as follows:

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IN THE

UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 23,812

THE ENVIRONMENTAL DEFENSE FUND, INC., IRENE LOPEZ, ELVIRA GARDUNO, KATHY RADKE, MARILYN VITTOR, LEIGH ROYCROFT, and JUAN ZAMORA,
Petitioners,

v.

ROBERT H. FINCH,
Secretary, Health, Education and Welfare,
Respondent.

ON PETITION FOR REVIEW OF AN ORDER OF THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

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AUTHORITIES CITED

IN THE

UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 23,812

THE ENVIRONMENTAL DEFENSE FUND, INC., IRENE LOPEZ, ELVIRA GARDUNO, KATHY RADKE, MARILYN VITTOR, LEIGH ROYCROFT, and JUAN ZAMORA,
Petitioners,

v.

ROBERT H. FINCH,
Secretary, Health, Education and Welfare,
Respondent.

ON PETITION FOR REVIEW OF AN ORDER OF THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

REPLY BRIEF FOR PETITIONERS

I

At the outset it is essential that the independent responsibilities of the Secretaries of Agriculture and Health, Education and Welfare be clarified. Through the art of confusion the government would have this Court believe that there is before it a sympathetic and concerned Secretary whose hands are tied until such time as the Agriculture Department acts. This is a complete distortion of the interplay between the Food, Drug and Cosmetics Act and the Federal Insecticide, Fungicide, and Rodenticide Act.

In point of fact the thrust of the responsibility of each of the Secretaries is quite different. In passing on the propriety

of registration or deregistration the Secretary of Agriculture is concerned with (1) the efficacy of the pesticide for its intended use and (2) the environmental consequences of such use. HEW's mandate is quite independent of Agriculture's concerns: it is the effect on human health of any residues that may remain on food when it reaches the consumer.[1] Although often times the factors relevant to each of these independent responsibilities will merge that need not always be the case. For example, a fungicide applied in a warehouse or a pesticide applied in a hot house may be efficacious and need not occasion any adverse environmental consequences. Nevertheless, the public health dangers of such applications may require the Secretary of HEW to establish a zero tolerance for residues.

By obscuring this clear division of authority and engaging in administrative "buck-passing" HEW seeks to preclude any action on its part. But this ignores the fact that the authority of the Secretary of HEW to repeal tolerances (or significantly lower them) would be meaningless if it is to be read as dependent upon deregistration action by the Secretary of Agriculture. Once Agriculture deregisters a pesticide there is little need for HEW to be concerned over residue tolerances. The whole point of HEW's responsibility is to act as necessary to protect the public health in the face of an *existing* registration. Indeed, the government appears to recognize this fact which is inherent in the past actions of the Secretary reducing DDT tolerances. (Resp. Br. p. 33).

The second major obfuscation in the government's brief relates to its characterization of petitioners' position. We do not ask the Secretary to do the impossible and we do

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[1] It is surprising that the Secretary of HEW, who has responsibility for insuring the integrity of our food supply, would even suggest that the limited cancellation proceedings initiated by the Department of Agriculture represents all the action that is now appropriate. That's fine for those who eat shade trees, tobacco, household bugs and aquatic life.

not contend that the Delaney amendment requires realization by the Secretary of that which is beyond his competence. We have not asked the Secretary to remove DDT and its metabolities from the environment. We have asked merely that he exercise his full authority to protect humans from the unnecessary ingestion of those carcinogens on raw agricultural commodities. This is what Delaney requires: to do what is possible.

The government takes the position that Delaney, literally applied, requires the seizure of any raw agriculture commodity containing a carcinogen and since this would, as a consequence of the environmental contamination of DDT, threaten our entire food supply, the Secretary need do nothing. That is, that the option open to the Secretary is either to apply Delaney unreasonably or to ignore it.

We do not ask that the Secretary threaten this nation's food supply. We do suggest, however, that the spirit of Delaney can be applied without imposing any such threat. The spirit of Delaney requires that the Secretary do that which is possible: that he do as much as he reasonably can to protect the public from the inclusion of carcinogens in the food which we eat. This, and not the total elimination of DDT from the environment, is what we have asked the Secretary to do. In our supplemental petition we requested that (App. A-95):

> At a minimum, the Secretary should establish a zero tolerance for DDT and its residues on all raw agricultural commodities with the possible exemption from seizure of any commodities in which it can be established that any residues are the consequence of applications of DDT that were made prior to the announcement by the Secretary of the zero tolerance.

In effect we have asked the Secretary to establish, for confiscation purposes, a tolerance which takes account of environmental contamination. This is precisely what the Secretary did when he established the DDT tolerance for milk. In 1967, pursuant to a petition filed by the California

Departments of Public Health and Agriculture, HEW established a tolerance for DDT and its metabolites in milk at .05 ppm (parts per million) precisely to take into account environmental contamination; the regulation makes clear that "[t]hese tolerances are not established to provide for residues from the purposeful use of DDT, DDD, or DDE on dairy cattle, in dairy barns, or on the crops intended to be used for feeding dairy cattle." 21 CFR 120.147c.[2]

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[2]It is noteworthy that the California petition requested that the residues of DDT, DDD and DDE each be set at .05 ppm but in combination that the permitted residue level be set at 1.0 ppm. HEW refused to permit a higher tolerance for combinations. This demonstrates that the petitioner need not contend for the solution ultimately deemed appropriate but rather that the petition is to be subject to reformation in the context of an evidentiary hearing.

Pursuant to the California petition HEW appointed an advisory committee. It is significant that the advisory committee recognized that:

> * * * the wide usage of DDT over a number of years and at the present time, the chemical stability of DDT and its metabolites, and drift from spraying operations, have all contributed to unavoidable contamination of dairy products in spite of vigorous educational programs and enforcement procedures to reduce such contamination to a minimum. In addition, the use of more sensitive analytical methods resulted in the detection of amounts of residues previously unknown to occur in many products. The problem of inadvertent contamination of milk by widely used, persistent pesticides is not unique to DDT. Thus an existing situation must be recognized and controlled with the understanding that pesticide-free raw milk is a practical impossibility at the present time. [Report of the Food and Drug Administration's Advisory Committee Appointed to Review the Petition of the California State Departments of Public Health and Agriculture to Establish a Tolerance for DDT and Related Compounds (DDD and DDE) in Milk and Milk Products, October 26, 1966.]

When the Delaney amendment was enacted the state of the art of scientific surveillance did not permit the detection of fractional parts per million. It was therefore possible to apply Delaney literally. Since the enactment of Delaney, the perfection of gas chromatography, the new method which can now measure fractional parts per million, may indeed have made it impossible to find a commodity that contains no trace of DDT. But this does excuse action under Delaney for it was always understood that application of that amendment was to be sensitive to the state of the art. (See *infra* p. 6).

It follows, therefore, that the Secretary of HEW can act to significantly protect the public health whether or not any action is taken by the Secretary of Agriculture. He can establish residues for DDT that provide only for environmental contamination and in this way reasonably effectuate the requirements of Delaney.

II

Respondents have attempted, by lengthy argument, to deny the applicability of the Delaney clause to pesticides. We feel that our brief, at pp. 11-28, effectively deals with that denial.[3] We would only add that if Congress agreed with respondent's position, it would have immediately amended the pesticide provision to prohibit application of the Delaney clause. When Secretary Flemming testified at length that HEW had interpreted the pesticide section as

[3]We are compelled to direct the Court to a deceptive quotation in Respondents' Brief. At footnote 15, page 19, the government states that Secretary Flemming, in commenting on the cranberry seizures, stated: "...the earlier Pesticide Amendment, which is applicable to the cranberries, does not contain such a specific provision....". The full sentence, inserting the language conveniently omitted by the government, is as follows: "Even though the earlier Pesticide Amendment, which is applicable to the cranberries, does not contain

including an "implied" Delaney clause. Congress, on the contrary, praised HEW for that interpretation. (Pet. Br. pp. 24-27).

Respondent's appeal to the previous construction of the Delaney clause by six Federal judges (Resp. Br. pp. 17-18) is neither supportive of their arguments nor damaging to ours. First, neither *Bell v. Goddard*, 366 F.2d 177 (CA 6, 1966 nor *Rossi v. Finch*, ____ F.Supp. ____ (N.D. Cal., 1970) considered the applicability of the Delaney clause to the pesticide provision. Second, to accept Respondent's position that the Delaney clause applies only to *pending* petitions would mean that if evidence of carcinogenicity was forthcoming *one day* after a petition was approved, HEW would then be powerless to act. That is arrant nonsense. See H.R. Rep. No. 1761, 86th Cong., 2d Sess. 1960, U.S. Cong. Code & Adm. News, 1960, pp. 2934-36.

III

Respondent believes that its reference and deference to its own in-house advisory committee (the Mrak Commission) can be substituted for an open, public hearing operating under the traditional procedures for the distillation of fact from opinion:

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such a specific prohibition, the same principle has been applied.". HEW, News Release, November 9, 1959.

The quotation in that footnote from H.R. Rep. No. 1761, 86th Cong., 2d Sess. (1960) is also seriously out of context. The full quotation should read:

> According to advice of our scientists, the principle of the above-quoted anticancer (Delaney) proviso of the Food Additives Amendment reflects, basically, the current state of scientific knowledge, and we would therefore, except as noted below, feel constrained to apply the same principle even in the absence of this proviso, and we do in fact apply it in the administration of the Pesticide Chemicals Amendment which does not contain the proviso.

> "On the basis of the recommendation in the Mrak Report, the Commissioner, on December 8, 1969, notified petitioners that their pesticide petition was not acceptable for filing [Resp. Br. p. 10]."

The Congressionally mandated right to the administrative procedure for amendment of pesticide tolerances, *even if* sought by someone *other than* a pesticide manufacturer, cannot be so conveniently ignored.

CONCLUSION

We therefore urge that this Court:

1. Affirm the uncontested fact that DDT is a carcinogen.

2. Affirm the long-standing interpretation that the Delaney principle is applicable to pesticides.

3. Remand this matter to HEW with directions that it implement the Delaney anticancer amendment to the maximum extent feasible.[4]

Respectfully submitted,

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[4] Respondent appears to question petitioners' standing (footnote 13, page 10). In response we merely refer to Appendix pages A 5-8 and A 65-68 where the substantial interest of each of the petitioners is set out. See also: *Association of Data Processing Service Organizations, Inc. v. Camp.*, ____ U.S. ____ (No. 85, March 3, 1970); *Barlow v. Collins*, ____ U.S. ____ (No. 249, March 3, 1969); *Scanwell Laboratories, Inc. v. Thomas*, ____ U.S.App.DC ____, ____ F.2d ____ (CADC, February 13, 1970).